

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

- - -

4 IN RE: NATIONAL : HON. DAN A.
5 PRESCRIPTION OPIATE : POLSTER
6 LITIGATION :
7 :
8 APPLIES TO ALL CASES : NO.
9 : 1:17-MD-2804
10 :
11 :

12 - HIGHLY CONFIDENTIAL -

13 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

14 VOLUME I

15 - - -

16 December 5, 2018

17 - - -

18 Videotaped deposition of
19 GARY J. VORSANGER, Ph.D., M.D., taken
20 pursuant to notice, was held at the law
21 offices of Drinker Biddle & Reath, 105
22 College Road East, Princeton, New Jersey,
23 beginning at 9:26 a.m., on the above
24 date, before Michelle L. Gray, a
25 Registered Professional Reporter,
26 Certified Shorthand Reporter, Certified
27 Realtime Reporter, and Notary Public.

- - -

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4

5 Testimony of:

6 GARY J. VORSANGER, Ph.D., M.D.

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5 Direction to Witness Not to Answer

6 PAGE LINE

None.

7

8 Request for Production of Documents

9 PAGE LINE

None.

10

11 Stipulations

12 PAGE LINE

None.

13

14 Questions Marked

15 PAGE LINE

None.

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- - -

2

THE VIDEOGRAPHER: We are

3

now on the record. My name is

4

Henry Marte. I'm a videographer

5

with Golkow Litigation Services.

6

Today's date is December 5,

7

2018, and the time is 9:26 a.m.

8

This videotaped deposition

9

is being held in Princeton, New

10

Jersey in the matter of National

11

Prescription Opiate Litigation.

12

The deponent today is Dr.

13

Gary Vorsanger.

14

All appearances are noted on

15

the stenographic record.

16

The court reporter, Michelle

17

Gray, will now administer the oath

18

to the witness.

19

- - -

20

... GARY J. VORSANGER, Ph.D., M.D.,

21

having been first duly sworn, was

22

examined and testified as follows:

23

- - -

24

EXAMINATION

1

- - -

2 BY MS. CONROY:

3 Q. Good morning, Doctor. My
4 name is Jayne Conroy. I represent the
5 plaintiffs in this case. And we're here
6 today in Princeton, New Jersey; is that
7 correct?

8 A. Correct.

9 Q. Have you ever been deposed
10 before?

11 A. I have not.

12 Q. Okay. I'm sure your lawyer
13 gave you some of the ground rules, but if
14 at any point you don't understand what
15 I'm asking, you can ask me to rephrase or
16 if you can't hear me, let me know, or if
17 you need a break, let all of us know and
18 don't forget to unplug yourself from the
19 microphone, which we will forget to do.
20 But we'll try and remind you.

21 The only thing I think we
22 ask is that if I'm asking a question, you
23 wait until I finish. And then I will try
24 not to step on your answer when I'm

1 asking questions. It makes it easier for
2 the court reporter for the record.

3 A. Okay.

4 Q. Who is your current
5 employer?

6 A. So I'm currently
7 self-employed.

8 Q. Okay. And do -- is it -- do
9 you have a corporation or any sort of a
10 business?

11 A. I have an LLC.

12 Q. Okay. And what's the name
13 of it?

14 A. It's Crossroads Medical and
15 Scientific Consulting LLC.

16 Q. And what is the business of
17 Crossroads Medical and Scientific
18 Consulting?

19 A. Medical and scientific
20 consulting predominately to the
21 pharmaceutical industry.

22 Q. What kind of consulting?

23 A. So if there were questions
24 about clinical trial design or things

1 like that, that companies were needing
2 additional help on, then I'm able to, you
3 know, provide those type of support
4 services to them.

5 Q. Okay. And how long have you
6 had that business?

7 A. It really began the
8 beginning of this year, 2018.

9 Q. Do you have any clients
10 currently?

11 A. I do not at the current
12 time.

13 Q. Have you had any since you
14 started the business?

15 A. I have not.

16 Q. Let me show you what I've
17 marked as Exhibit 1.

18 (Document marked for
19 identification as Exhibit
20 Janssen-Vorsanger-1.)

21 BY MS. CONROY:

22 Q. And let me just explain to
23 you. If I'm going to be asking you
24 questions today about any documents,

1 typically I will mark them as an exhibit.
2 You see there's a sticker there on the
3 bottom?

4 A. Yes.

5 Q. And hand them to you and
6 your lawyer will have a copy as well.

7 And for purposes of
8 potentially any of the jurors or the
9 judge watching this video, they'll also
10 see it on a screen, it's just a little
11 bit hard for us to see it on the screen
12 here in the room. But thankfully we have
13 hard copies.

14 Have you ever seen this
15 document before, Exhibit 1, which is the
16 amended deposition of Gary Vorsanger?
17 It's a deposition, we call it a
18 deposition notice.

19 A. I have not.

20 Q. When did you first hear
21 about this deposition, that there would
22 be a deposition of you?

23 A. So I was contacted from one
24 of the Johnson & Johnson attorneys

1 letting me know that I was being deposed.

2 Q. And I'm sure your lawyer has
3 cautioned you. I don't want you to tell
4 me anything that you have -- any
5 discussions you've had with your lawyers.
6 Okay?

7 A. Right.

8 Q. I just want to caution you
9 in case you blurt out, Mr. Lifland will
10 object if he thinks that may happen.
11 Okay?

12 A. Okay.

13 MR. LIFLAND: But you're
14 free to -- you're free to say you
15 were contacted at such and such a
16 date or you met with us at such
17 and such a date. Just don't
18 disclose the substance of any
19 conversations you've had.

20 THE WITNESS: Okay.

21 BY MS. CONROY:

22 Q. Okay.

23 Approximately how long ago
24 was that phone call?

1 A. Sometime in July of this
2 year.

3 Q. And have you had any
4 face-to-face or telephone conferences
5 since that date about this deposition?

6 A. Yes.

7 Q. Okay. Have you had any
8 face-to-face meetings?

9 A. Yes.

10 Q. And were they to prepare you
11 for this deposition?

12 A. Yes.

13 Q. And how many did you have?

14 A. Several.

15 Q. Did they begin sometime in
16 July?

17 A. There was some discussion,
18 but the preparation for this took place
19 later on.

20 Q. Okay. Where do you live,
21 what city?

22 A. I'm sorry?

23 Q. Where do you live?

24 A. Oh, I live in Yardley, PA,

1 Pennsylvania.

2 Q. Pennsylvania?

3 A. Yeah.

4 Q. How far away is that?

5 A. From Princeton?

6 Q. Yes.

7 A. About, about 40 minutes plus
8 or minus.

9 Q. Okay. So it's -- you can
10 drive here?

11 A. Yes.

12 Q. To where -- to where the
13 deposition is?

14 A. Yes.

15 Q. And where were the meetings
16 held?

17 A. The meetings were held in
18 Titusville, New Jersey.

19 Q. And how far away is
20 Titusville from Princeton where we are
21 today?

22 A. I'm not sure. It's -- it's
23 easily within travel distance by car.

24 Q. Okay. And so could you

1 drive to Titusville from Yardley?

2 A. Yes, it's close.

3 Q. And were they full day
4 meetings?

5 A. I didn't keep track of the
6 time, but they -- they went on for a
7 little while.

8 Q. Did you review any documents
9 at those meetings?

10 A. Yes.

11 Q. Did you bring any documents
12 to those meetings, documents that were in
13 your possession?

14 A. I don't recall. I don't
15 think so.

16 Q. When did -- when were you
17 last employed by Johnson & Johnson?

18 A. I retired from Johnson &
19 Johnson on June 30, 2017.

20 Q. And when you retired, did
21 you bring any files home with you or have
22 any hard copies of any documents from
23 Johnson & Johnson?

24 A. No, I did not.

1 Q. What about an e-mail
2 address. Did you retain a Johnson &
3 Johnson e-mail address?

4 A. No, I did not.

5 Q. Did you retain any
6 electronic files from your years of
7 employment at Johnson & Johnson?

8 A. No. I have no files from my
9 work at J&J.

10 Q. What about copies of things
11 like posters that were presented at the
12 American Pain Society or any other types
13 of posters that you worked on that you
14 presented, do you have copies of those at
15 home?

16 A. I do not. No, those were --
17 I did not take those with me.

18 Q. Okay. What about any
19 publications, copies of publications that
20 you authored or co-authored with others?

21 A. No, I didn't take any of
22 those documents either.

23 Q. And I mean -- when you say
24 no documents, that means electronic as

1 well?

2 A. Correct. Printed and
3 electronic.

4 Q. Okay. Who was present at
5 the -- these deposition preparation
6 meetings?

7 A. My attorneys.

8 Q. And who are they?

9 A. There were attorneys from
10 O'Melveny & Myers.

11 Q. And when you said your
12 attorneys, are they your personal
13 attorneys?

14 A. The attorneys for Janssen
15 and for myself.

16 Q. And do you know their names?

17 A. Yes. They are sitting with
18 us now.

19 Q. Okay. So Mr. Lifland?

20 A. Yes.

21 Q. And, I'm sorry --

22 MR. LIFLAND: Weisband,

23 W-E-I-S-B-A-N-D. Vincent

24 Weisband.

1 BY MS. CONROY:

2 Q. You can put the notice away.

3 Dr. Vorsanger, I have a
4 picture of you. Is that --

5 A. Yes.

6 Q. -- your picture?

7 A. It is.

8 Q. Okay. I'm going to put it
9 here, because I'm just going to write
10 down some of your credentials.

11 You are a medical doctor,
12 correct?

13 A. That's correct.

14 Q. And when did you graduate
15 from medical school?

16 A. 1984.

17 Q. And whereabouts?

18 A. Mount Sinai School of
19 Medicine.

20 Q. And where was your
21 residency?

22 A. When I attended medical
23 school?

24 Q. Yes.

1 A. I lived in Manhattan. New
2 York.

3 Q. And I saw that you are board
4 certified in what practice areas?

5 A. I'm board certified in both
6 internal medicine and in anesthesiology.

7 Q. Have you ever prescribed an
8 opioid for a patient?

9 A. Yes.

10 Q. And did you do that -- what
11 years did you do that?

12 A. I would have done it when I
13 worked during my training in internal
14 medicine. If I worked in the emergency
15 room, I may have written some
16 prescriptions for patients for opioid
17 pain medications at that point also.

18 Q. Would that -- would that
19 have been in the -- in the late '80s,
20 early '90s?

21 A. That would have been, yes,
22 that would have been from '84 to '87 or
23 thereabouts.

24 Q. Okay. And what opiates were

1 available to prescribe from '84 to the --
2 '84 to '87?

3 A. I don't recall. I'd have to
4 check.

5 Q. Were there long-acting
6 opioids at that time?

7 A. It would have been short, I
8 think. I believe. Immediate release.

9 Q. What -- what about modified
10 release opioids, would they have been
11 available at that time?

12 A. I don't recall prescribing
13 such medications. I might have written a
14 prescription for one of those, but I
15 don't recall.

16 Q. And for what indications
17 would you have prescribed a short-acting
18 opioid from '84 to '87?

19 A. If patients would have -- if
20 I would have seen them in the emergency
21 room and they presented with any kind of
22 muscle pain, sports trauma, something
23 like that.

24 Q. So for -- not for a

1 malignant or cancer pain, but you would
2 have prescribed for some sort of a pain
3 or chronic pain condition?

4 A. Correct.

5 Q. Did you have any patients
6 that were taking short-acting opioids
7 from '84 to '87 that took them on a
8 regular basis?

9 A. I'd have to review my
10 records. I don't recall.

11 Q. Did you have -- I know you
12 mentioned the emergency room. Did you
13 have patients that you followed from '84
14 to '87?

15 A. I did. When I -- when I was
16 doing my internal medicine training I
17 would have had a medical clinic.

18 Q. And where was that located?

19 A. Montefiore Hospital in New
20 York, in Bronx, New York.

21 Q. And was that from '84 to
22 '87?

23 A. Yes, I believe so. The
24 dates are approximate.

1 Q. That's fine. It might help
2 a bit. Let me mark as the next exhibit.

3 (Document marked for
4 identification as Exhibit
5 Janssen-Vorsanger-2.)

6 BY MS. CONROY:

7 Q. What I've marked as
8 Exhibit 2 is what appears to be, and I'm
9 going to ask you about it, a CV or
10 resumé. And the Bates range is
11 JAN-MS-02320343 through 354. Does this
12 look like your CV, Dr. Vorsanger?

13 A. Yes, I'm reviewing it now.

14 Q. Okay.

15 A. Yes, this appears to be a
16 copy of a version of my CV.

17 Q. And would you have prepared
18 it?

19 A. Yes, I would have.

20 Q. Okay. And would it be fair
21 to say this -- well, can you -- it says
22 that it goes from August 2013 to the
23 present. Do you see under where it says
24 you were therapeutic head?

1 A. So I was the therapeutic
2 area lead for analgesia from -- and the
3 dates are approximate, from August 2013
4 until from U.S. rights for Nucynta were
5 sold in the range of 2015, thereabouts.
6 I don't have the exact dates in 2015.

7 Q. Okay. Do you think that
8 this CV covers up through that point in
9 2015? Is there a way you can -- is there
10 way you can tell what date -- the end
11 date of this CV?

12 A. So the end date of this CV
13 would have been -- you mean what I'm
14 defining as present?

15 Q. Correct.

16 A. Mm-hmm. No, I don't have
17 that. I would have to just define my
18 time as the therapeutic area lead for
19 analgesia for the dates that I've already
20 given you, approximate dates.

21 Q. Okay. So it would not be
22 later than some month in 2015?

23 A. No, not for Nucynta.

24 Q. So if we look toward the

1 back on the page -- and just so, what we
2 might do during this deposition is
3 refer -- these are Bates numbers down
4 here in the bottom right-hand corner. So
5 if you turn to Page 349.

6 MR. LIFLAND: Just in case
7 the witness doesn't know what a
8 Bates number is, let's just
9 explain. It's a number that when
10 we produce the documents, we stamp
11 just for our recordkeeping. It's
12 not part of the original document.

13 THE WITNESS: Okay.

14 MR. LIFLAND: But it helps
15 us find the pages and the
16 documents that don't otherwise
17 have numbers.

18 THE WITNESS: Okay. Thank
19 you. All right.

20 BY MS. CONROY:

21 Q. And I think this is -- you
22 were talking about your internship and
23 residency in the Bronx at Montefiore, and
24 that was from '84 through --

1 A. So --

2 Q. -- '87?

3 A. Right. So if you look under
4 internship and residency, it's exactly as
5 you said, Counsel. '84 to '87. And then
6 I had a second residency, and that
7 described my time as an intern and
8 resident in internal medicine,
9 culminating in me being board-certified
10 in internal medicine.

11 And from 1987 to 1990 I did
12 a second residency in anesthesia in
13 Boston at the Massachusetts General
14 Hospital.

15 Q. And did you see -- did you
16 have patients of your own from 1987 to
17 1990 when you were doing your anesthesia
18 residency?

19 A. I'm not clear on what the
20 question would be.

21 Q. Did you have -- did you --
22 did you see patients to treat particular
23 patients during that residency?

24 A. Most of those -- are you

1 asking did I treat patients and
2 administer opioid analgesics during that
3 time or did I have a clinic?

4 Q. Well, I wasn't being that
5 specific.

6 A. Okay.

7 Q. Did you -- were -- did
8 you -- were you employed by a hospital
9 and using anesthesia in surgical suites
10 or did you actually see patients and
11 treat them for whatever conditions -- any
12 condition at all?

13 A. Yes. I worked in a hospital
14 and treated patients administering
15 anesthesia in surgical suites during that
16 time.

17 Q. Okay. Did you have occasion
18 to prescribe any opioid analgesics to
19 individual patients for conditions other
20 than surgical anesthesia at that time?

21 A. Not very much. Most of it
22 was operating room work.

23 Q. And then where did you go
24 after 1990?

1 A. So from 1990 to 1993, I
2 worked as -- I was invited to come on
3 staff, and I was a staff anesthesiologist
4 at the Massachusetts General Hospital.

5 Q. And I think if we go one
6 page earlier, 348, we can see that you
7 had, from 1990 to 1993, you were an
8 assistant in anesthesia at Mass General.
9 And then from '93 to '95 you became a
10 staff anesthesiologist at Concord
11 Hospital in Concord, New Hampshire; is
12 that correct?

13 A. Yes.

14 Q. Okay. Did you see patients
15 outside of surgical anesthesia when you
16 were at Concord Hospital?

17 A. No.

18 Q. And then where did you go
19 from Concord Hospital?

20 A. So in 1995, I transitioned
21 over to the pharmaceutical industry, and
22 I started working at Astra USA.

23 Q. And what is Astra USA?

24 A. Astra USA was a company

1 that -- eventually Astra merged with
2 AstraZeneca. But prior to that Astra USA
3 was a US -- a subsidiary of Astra.

4 Q. And what were your -- and
5 that was in Westborough, Massachusetts?

6 A. Yes.

7 Q. And your title was medical
8 advisor, hospital division; is that
9 correct?

10 A. That's correct.

11 Q. And you did that for about
12 two years from February '95 to March of
13 '97?

14 A. Yes. Approximately. Again,
15 the dates are approximate.

16 Q. Okay. And could you
17 describe for me what your -- what your
18 responsibilities were at Astra?

19 A. Yes. Astra was developing a
20 new local anesthetic at that time. And
21 so I provided -- based on my clinical
22 expertise, provided information to them
23 to help them develop various documents to
24 inform prescribers about the medication

1 as well, amongst other things.

2 Q. Had you -- had you done
3 something like that before?

4 A. No. This is my first
5 opportunity to be a consultant and to
6 work with a company.

7 Q. And was the local anesthetic
8 already approved by the FDA or was it in
9 the process of becoming approved?

10 A. I don't recall at this
11 point. It was close to approval. It may
12 have been approved. I think it was
13 peri-approval. But I don't recall.

14 Q. Okay. And let's just -- I
15 think you listed out where you have R&D
16 here.

17 And you said you advised the
18 company.

19 A. Yes.

20 MR. LIFLAND: You're
21 referring to a different page than
22 the one he's got open there.

23 BY MS. CONROY:

24 Q. Oh, I see. So one -- go one

1 page earlier.

2 MR. LIFLAND: One page
3 prior.

4 BY MS. CONROY:

5 Q. 347.

6 A. Yes, thank you.

7 Q. Do you see where it has
8 Astra USA?

9 A. Yes. I would have -- yes.
10 So a part of it would have been to
11 develop certain protocols for them, if
12 they were doing clinical studies as well.
13 So that was all part of my advising that
14 we talked about, advising the company
15 based on my expertise.

16 Q. Okay. Had you participated
17 in a clinical trial prior to your
18 employment at Astra?

19 A. I would have -- as part of
20 my activities when I was a resident at
21 Mass General, some of my attending
22 physicians may have been conducting
23 clinical trials, and I might have been
24 providing patient care under their

1 direction as part of clinical trials
2 activities.

3 Q. Did you -- prior to your
4 work at Astra USA, did you ever seek, for
5 example, something like IRB approval for
6 a clinical trial?

7 A. No, I did not.

8 Q. Okay. Did you ever work to
9 secure consent from patients for a
10 clinical trial prior to Astra?

11 A. I don't recall whether I did
12 those activities, as I just described
13 when I was at Mass General working with
14 attending physicians on their studies. I
15 don't recall.

16 Q. Okay. Were you ever listed
17 as an investigator in a clinical trial,
18 do you know, while you were at Mass
19 General?

20 A. No, I was not.

21 Q. Were you listed as an
22 investigator in any clinical trials while
23 you were at Astra USA?

24 A. No, I was not.

1 Q. Okay. Did you ever secure
2 IRB approval for any clinical trials
3 while at Astra?

4 A. No.

5 Q. Do you know if IRB approval
6 was secured for the clinical trials that
7 were being conducted at Astra that you
8 were involved in?

9 A. They would have been as a
10 matter of course for the company.

11 Q. Do you personally know if
12 they were?

13 A. I don't know that for a
14 fact, but that would have been part of
15 the process in doing studies at that
16 time, or continuing even to today.

17 Q. Was -- I'm probably not
18 pronouncing it correct. Naropin, was
19 that the drug that you were working on?

20 A. Yes, Naropin.

21 Q. Naropin?

22 A. Naropin, yes.

23 Q. And that was the local
24 anesthetic?

1 A. Correct.

2 Q. Okay. And then the next
3 bullet point says you created and
4 reviewed research protocols for Phase III
5 commitments for two local anesthetics.
6 One was a neurological drug, and the
7 other was an intravenous -- intravenous
8 cardiovascular drug. Were either of
9 those Naropin?

10 A. I don't recall.

11 Q. Was Naropin a neurological
12 drug? Do you know?

13 A. I don't recall.

14 Q. Do you recall what Naropin
15 was used for?

16 A. It's a local anesthetic.
17 But -- so I'm not sure exactly what my
18 reference is. At that point, whether
19 there was another medication that I was
20 thinking of, I just -- I don't recall.

21 Q. Okay. You have a bullet
22 point that you revised packaged --
23 package inserts?

24 A. Yes.

1 Q. What do you mean by that?

2 A. So if there was a request
3 from the FDA to take a look at package
4 inserts and possibly make -- update them
5 with warnings or precautions, et cetera,
6 then I would have provided my expertise
7 as an anesthesiologist working with
8 physicians, working at the company to
9 revise the package insert.

10 Q. So if I understand you
11 correctly, if the FDA had requested an
12 update, you would then go and speak to
13 clinicians about what?

14 A. So if FDA -- if FDA had
15 requested an update of the company, then
16 the company physicians would have reached
17 out to me, based on my background and
18 expertise and use of local anesthetics to
19 provide them with some information about
20 current usage and appropriate usage of
21 the medication, and so that was
22 consult -- one of the consulting roles
23 that I would have had to the company.

24 Q. Is it also correct that if,

1 in your role with the company you had
2 identified some issue with one of the
3 local anesthetics or -- or any other
4 product you were working on, that's
5 something that you could yourself or your
6 company could bring to the FDA?

7 A. I'm not sure I understand
8 your question.

9 Q. I think you've mentioned
10 that if the FDA wanted a change to the
11 package insert --

12 A. Right.

13 Q. -- that you could then go
14 out -- you would then go out and discuss
15 with clinicians whatever that change
16 should be?

17 A. Not necessarily. My only
18 experience with administering local
19 anesthetics was an expertise that I would
20 bring to the company if they had
21 questions. Company physicians could --
22 or other people at the company could
23 reach out to clinicians as well. But
24 this was somewhat to provide counseling

1 to the inhouse physicians.

2 Q. Did you just say -- to
3 provide counseling to the inhouse -- to
4 the inhouse physicians?

5 A. Yes. So they had employee
6 physicians working at the company. They
7 were not anesthesiologists. Didn't have
8 expertise in local anesthetics.

9 So if they had questions or
10 they needed advice on how you would
11 administer a local anesthetic, to which
12 would be appropriate patients, those are
13 the types of questions that I could help
14 them with to provide that background.

15 In addition, they would
16 reach out to their own clinical experts
17 working outside the company as well.

18 Q. And would that be to assist
19 in the revision of a package insert for
20 that local anesthetic?

21 A. It could be, if that was the
22 activity that was going on.

23 Q. And my question is, I
24 understood you to first reference that

1 the FDA would have requested a revision
2 to a package insert, but what I would
3 like to know is whether or not it was
4 possible for Astra to revise the package
5 insert without consulting -- with --
6 without hearing first from the FDA?

7 A. Yes. If the company became
8 aware of new safety information or new
9 additional clinical information, they
10 would be in touch with FDA and engage in
11 a dialogue to say this is some of the
12 information that they would like to
13 include in the package insert as an
14 update. And then they would agree with
15 FDA with that type of information. So
16 they could reach out proactively if they
17 wanted to. But the changes to the
18 package insert would have to be done in
19 agreement with FDA.

20 Q. Sure. But it -- if you or
21 any of the inhouse physicians were being
22 made aware of some problem out in the
23 field with that local anesthetic, you
24 could then contact the FDA about that?

1 A. We -- we could -- yes, we
2 could contact the FDA. We would contact
3 the company and make them aware of what
4 we've observed. And the company would
5 then engage in a dialogue with the FDA.

6 Q. In fact, you would be
7 required to do that?

8 A. Yes. If there was --
9 especially if it was safety issues.

10 Q. And is that true even today?

11 A. Yes.

12 Q. One of the bullet points
13 here is "attended investigators meetings
14 for two drugs."

15 What does that mean?

16 A. So if there were clinical
17 studies that were being anticipated for
18 compounds, then there would be meetings
19 that would be convened with the clinical
20 investigators who would be participating
21 in the study. And at those types of --
22 those are investigator meetings. And at
23 those meetings they would review the
24 safety profile of the drug, review the

1 protocol of the drug, again, and how to
2 had administer the drug safely and
3 effectively.

4 Q. And then the next bullet
5 point says, "Helped to recruit leading
6 physician scientists for clinical
7 trials."

8 What -- can you explain to
9 me how you helped do that?

10 A. So if there was an interest
11 in conducting a clinical trial with local
12 anesthetics, some of the people who a
13 company might be interested would be
14 clinicians who have experience with
15 clinical trials, as well as with the
16 compound. And if these were people that
17 I know, I would have been able -- asked
18 by the company to reach out and explain
19 the protocol to them, the intent of the
20 study, and the design, and discuss and
21 see if there was interest. This was
22 being done with other people at the
23 company besides myself. But this was --
24 would be one of the activities that could

1 go on as part of physician recruitment
2 for participating in controlled clinical
3 trials.

4 Q. And would you -- by recruit,
5 you would -- you would go out and
6 interview those physicians or those
7 physician scientists to check, or to
8 review their suitability?

9 A. There would be suitability
10 studies to identify whether there was
11 interest, whether the -- whether the
12 sites themselves have the personnel to be
13 able to effectively conduct a clinical
14 trial safely and effectively.

15 And again, there were other
16 people at the company who would be doing
17 that as well. And I could provide some
18 information to them as requested, as part
19 of my consulting activities.

20 Q. Do you recall while you were
21 at Astra whether, in fact, you were --
22 and I understand it wasn't just you, you
23 may have been part of a team -- that you
24 did, in fact, recruit some physicians for

1 clinical trials?

2 A. I'm sorry, I don't
3 understand your question.

4 Q. Do you recall doing that at
5 AstraZeneca, recruiting physicians?

6 A. Yes, to be clear, it wasn't
7 AstraZeneca. It was Astra USA.

8 Q. I'm sorry, Astra.

9 A. I -- I don't recall specific
10 activities that I would have. I can't
11 think of specific physicians for example,
12 who we might have contacted at that
13 point. But these are activities that I
14 would have engaged in as part -- as part
15 of the discussion.

16 Q. And did Astra at that time
17 have physicians that were already known
18 to you that might be available for a
19 clinical trial?

20 A. I don't understand the
21 question.

22 Q. Would there have been -- if
23 you had -- if you were looking for
24 physicians to conduct clinical trials for

1 a drug that you were working on at Astra,
2 would there have been a list of
3 physicians to contact?

4 A. So are you asking whether
5 Astra would have had its own list of
6 investigators that they were interested
7 in, as well as people whom I might have
8 recommended?

9 Q. Well, I see that you say
10 that you helped recruit --

11 A. Yes.

12 Q. -- leading physicians.

13 So yes, I am asking if there
14 were already some physicians that Astra
15 had on a list or knew or had conducted
16 clinical trials in addition to physicians
17 that you might recruit.

18 A. I don't recall. But
19 typically companies would identify
20 clinicians or people whom they would like
21 to have participating in their clinical
22 trials. But I can't tell you that I
23 remember seeing a list, per se.

24 Q. Okay. And where you say

1 here, "Conducted initiation and site
2 visits"?

3 A. Yes.

4 Q. Is that of potential
5 clinical trial sites?

6 A. Yes.

7 Q. And then your final bullet
8 point here is that you "designed labeling
9 for a new local anesthetic after
10 consultations with former colleagues at
11 Mass. General Hospital and Brigham and
12 Women's Hospital."

13 What do you mean by designed
14 labeling?

15 A. So the new local anesthetic
16 was Naropin, ropivacaine, and when I
17 reached out to some of the -- of my
18 colleagues in those two institutions, as
19 we -- there is required labeling that FDA
20 had, but we were interested in
21 understanding what are some of the other
22 types of information that would be
23 clinically important to people who would
24 be administering local anesthetics to

1 patients, and to see whether that type of
2 information would be appropriate for a
3 product label, and then the -- then the
4 company would have engaged in
5 conversations with FDA to see whether
6 that type of information would, again, be
7 appropriate for a label, for a product
8 label.

9 Q. Next you have as a bullet
10 point, "Chairman, scientific and clinical
11 review committee." And it looks like
12 that included the review of requests for
13 support for postmarketing studies. Do
14 you see that?

15 A. Yes.

16 Q. What's a postmarketing
17 study?

18 A. A postmarketing study would
19 be a study of a medication after the
20 product had been approved -- for -- for
21 the U.S. here would be approved by the
22 Food and Drug Administration, and
23 worldwide it would have been for the
24 appropriate regulatory authority for that

1 country.

2 Q. And where it says,
3 "Reviewing all requests for support for
4 postmarketing studies," what does that
5 mean?

6 A. It means that individuals
7 would submit a -- either a protocol
8 concept or a paragraph or a summary of
9 the type of studies that they would like
10 to get support, financial support from a
11 company. And those would go through a
12 review committee.

13 And I was the chairperson
14 for that committee to review the study
15 design, make sure it was scientifically
16 valid, understand the patient population
17 that would be studied, and the endpoints
18 that they were interested in studying.

19 Q. And would you -- would you
20 yourself or with your team at Astra ever
21 actually draft protocols and then look
22 for clinicians to perform those
23 postmarketing studies?

24 A. I don't recall the

1 activities that would have occurred back
2 then.

3 Q. Is that -- is that typically
4 done by a pharmaceutical company, that
5 they may receive requests for
6 postmarketing studies as well as devise
7 postmarketing studies and then seek
8 clinicians to do them?

9 A. It depends on the point in
10 time. So today the companies, I think
11 for the most part, would not be engaged
12 in those activities.

13 At this time there may have
14 been an opportunity for companies to come
15 up with proposed designs to see if there
16 was interest. But I don't recall.

17 So there -- there may have
18 been changes in terms of the requirements
19 of what companies were permitted to do.

20 Q. Are companies not permitted
21 to do that now?

22 A. So today companies typically
23 for post -- when they receive support for
24 postmarketing studies, those work --

1 those would be studies that would be
2 information that would be submitted by --
3 by an investigator, it would be reviewed
4 by the company. It would be -- the
5 design and merit of it would be reviewed
6 by the company.

7 But the amount of input that
8 a company would basically be able to put
9 in today would -- might be very different
10 from what it would be in the '90s.

11 Q. Would it be more -- would --
12 would that input be more or less?

13 A. Today, less.

14 Q. And you say today. When
15 would that have started, that the input
16 would be less?

17 A. I don't recall.

18 Q. A year ago? Ten years ago?

19 A. Longer than that. I don't
20 have an exact date.

21 Q. Do you know why that is?

22 A. I can't tell you for sure.

23 Q. Can you tell me why you
24 think that is?

1 A. I think the intent was to
2 make sure that the companies funded it,
3 but that the ideas and the execution of
4 the study be done by the individuals for
5 whom who developed these protocols.

6 Q. So is it your understanding
7 then that the company itself would not be
8 devising the protocol, but the
9 individuals who approached the company
10 about a particular study would design the
11 protocols?

12 A. So just to be clear, we're
13 talking about postmarketing studies?

14 Q. Yes.

15 A. Yes, for postmarketing
16 studies, the idea would come from the
17 individual developing the protocol for
18 the postmarketing studies. There may be
19 interest from the company for that type
20 of work. But the actual developing of
21 the protocols and the execution of the
22 protocols would be done by the
23 investigator.

24 Q. And at some point earlier in

1 time it could be the company itself that
2 would design the protocol and then would
3 seek the investigator?

4 A. I don't -- I don't recall
5 that. I think there may have been
6 guidance, if it was requested by the
7 investigator. I don't recall the company
8 writing a protocol and handing it out. I
9 don't -- I don't know.

10 Q. Would the company have had
11 a -- had involvement in the writing of a
12 protocol?

13 A. That may have occurred,
14 again depending on the time that we are
15 talking about in the late '90s. That
16 might have happened.

17 Q. In any event, I think you
18 said at some point the company would
19 review the protocol; is that correct?

20 A. Correct, to make sure it's
21 scientifically valid, yes.

22 Q. And could the company, even
23 today, after review of a protocol, edit
24 the protocol?

1 A. I'm not sure what the
2 question means.

3 Q. I think you said that there
4 was less involvement in the creation of
5 protocols by companies. It was done by
6 the actual investigator who would then
7 approach the company, correct?

8 A. Yes.

9 Q. So my question is when the
10 investigator comes to the company with a
11 protocol, and the company reviews the
12 protocol, is the company -- can the
13 company revise the protocol or make
14 suggestions for changes to the protocol?

15 A. I think it depends on the
16 company. It would be a
17 company-to-company decision. So I
18 couldn't comment on what different
19 companies would have done back then or
20 even today. I just don't know.

21 Q. What about Johnson &
22 Johnson?

23 A. When we reviewed these --
24 these, we base -- these were either

1 reviewed and accepted or reviewed and
2 rejected.

3 Q. So Johnson & Johnson would
4 not have modified or revised protocols?

5 A. Johnson & Johnson would not
6 have modified or revised the protocols.
7 It may have asked if there were other
8 things that may or may not be of
9 interest, but no we did not write the
10 protocols.

11 Q. And was that true for your
12 entire tenure at Johnson & Johnson, as
13 far as you know?

14 A. I don't recall going back
15 what it was like. Certainly later on,
16 yes, that was true.

17 Q. We're going to be looking at
18 some documents with your time at Janssen
19 and Johnson & Johnson. So I might come
20 back to that a bit, because it might help
21 me with some of the dates.

22 A. Okay.

23 Q. Okay. You also say here,
24 you designed and implemented a new

1 evaluation process to include
2 statisticians, regulatory, and legal
3 personnel, pharmacists, and physicians.

4 What is that referring to?
5 It's the second bullet point.

6 A. When the -- we were
7 interested in having a certain structure
8 for the scientific and clinical review
9 committee. And we wanted to make sure
10 that the individuals reviewing it, that
11 there were a number of different
12 individuals as well. So statisticians
13 had always been part of the review, as I
14 recall. We didn't necessarily have a
15 pharmacist as part of the review
16 committee. So I added some other people
17 with different types of expertise to the
18 committee as well.

19 Q. And what is the -- what is
20 the function of the -- let me ask --
21 well, let me ask you this first.

22 It says scientific and
23 clinical review committee. Is that one
24 committee?

1 A. Yes.

2 Q. And what is the -- what is
3 the role of the scientific and clinical
4 review committee? And this is under your
5 Astra time. But is it different? Is
6 the -- is the scientific and clinical
7 review committee different from company
8 to company --

9 A. Yes.

10 Q. -- in your experience?

11 A. Yes.

12 Q. What was the -- what was the
13 purpose of the scientific and clinical
14 review committee at Astra?

15 A. To review postmarketing
16 studies.

17 Q. And this would be to review
18 protocols being presented by
19 investigative clinicians?

20 A. Correct.

21 Q. And then it says that you
22 worked with computer consultants to
23 develop a database to track ongoing
24 projects and adverse events. Do you see

1 that?

2 A. I do.

3 Q. And would this be ongoing
4 projects that were under the purview of
5 the scientific and clinical review
6 committee?

7 A. No. This would be other
8 projects that were going on at Astra. I
9 worked with a -- computer consultants to
10 develop a database to track the
11 activities themselves and to work to
12 ensure that we had adequate adverse event
13 reporting going on for all of those
14 activities.

15 Q. What kinds of activities?
16 Give me an example of what some of those
17 activities would be?

18 A. I don't recall at this
19 point.

20 Q. Would it be clinical trials?

21 A. The clinical trials would
22 have had their own processes in place at
23 Astra for reporting adverse events. So I
24 don't think necessarily that would have

1 been. But if there were other types of
2 activities that would be going on, other
3 projects that would make sure that that
4 information was being tracked, timelines
5 and that type of a thing.

6 Q. This -- I think that's what
7 I'm having difficulty with.

8 What kind of -- what kind of
9 projects other than a clinical trial
10 would you be tracking adverse events
11 within the company?

12 A. It would have been in parts
13 from the scientific review committee as
14 well, to make sure there was a correct
15 adverse -- an adequate adverse event
16 reporting.

17 Whether there were other
18 activities that were going on as well as
19 part of the work that went on at Astra in
20 the hospital division at that time, then
21 we would have wanted to make sure that
22 the people involved were reporting
23 adverse events.

24 Q. And these are adverse events

1 outside of clinical trials?

2 A. These are adverse events
3 outside of -- yes, right. The clinical
4 trials involved in the development of the
5 products would have had their own adverse
6 event reporting.

7 We wanted to make sure that
8 all the activities at the company where
9 there was a possibility that patients
10 would be exposed to the products, if
11 there were adverse events, that we were
12 capturing those accordingly and
13 appropriately.

14 Q. And could that have been,
15 for example, if a practitioner called
16 Astra and said they had a particular
17 problem with one of the Astra products,
18 are those the particular adverse event
19 that you'd be talking about?

20 A. Those would come through
21 their safety reporting group. Again,
22 those processes were running well. They
23 were in place as well. But if there were
24 other activities that might have a

1 clinical relevance that weren't actually
2 there, controlled clinical trials, it was
3 just again to make sure that they were
4 adequately capturing the adverse events.

5 Q. Okay. You also have a
6 section on marketing.

7 Do you see that?

8 A. Yes.

9 Q. And you have, "Established
10 and implemented budgetary guidelines for
11 postmarketing studies." Would you agree
12 with me that postmarketing studies can be
13 used to market a product, a drug?

14 A. Not necessarily. They would
15 have to be controlled clinical trials
16 where we have adequate level of evidence
17 that would be appropriate for the FDA so
18 that they could be used.

19 Q. So there would be very
20 specific guidelines with respect to a
21 clinical trial as to whether or not it
22 could be used for any promotional
23 activities?

24 A. The FDA has guidelines about

1 how -- what type of studies would need to
2 be done to be included in the label or
3 could be used for promotional activities.

4 Q. And has that changed over
5 time? Do you know?

6 A. Has the FDA changed?

7 Q. From -- well, I'm really
8 only interested, has it changed since
9 this bullet point when you were at Astra?
10 Has it changed over time from 1995 to the
11 present?

12 A. So is your question, has the
13 FDA implemented changes in the
14 requirements in the nature of what
15 information would be appropriate for use
16 in promotional activities between 1995
17 and 2018? Is that the question?

18 Q. Well, that's pretty general.
19 But I'm asking more with respect to
20 clinical trials and promotional
21 activities.

22 A. I'm sorry. I apologize.
23 I'm still not understanding the question.

24 Q. Sure. The FDA had -- in

1 1995, when you were at Astra, the FDA had
2 very strict requirements with respect to
3 what clinical trial results could be used
4 for promotional activities, correct?

5 A. Yes.

6 Q. And that's true today,
7 correct?

8 A. Yes.

9 Q. So do you recall any changes
10 that took place with respect to the FDA
11 guidelines from 1995 to the present with
12 respect to what -- the requirements of a
13 clinical trial or its results being used
14 for promotional activities?

15 A. I can't come up with
16 specific items, per se. But the rigor
17 certainly would have increased with time.

18 Q. So that the FDA would have
19 become stricter, correct?

20 A. Yes.

21 Q. But would you agree with me
22 that it was fairly strict in 1995?

23 A. Yes.

24 Q. Because it would require

1 that if any clinical trial results were
2 to be used for promotion, they would be
3 very strict guidelines as to what the
4 clinical trial had to look like, what
5 kind of result, what kind of oversight,
6 correct?

7 A. Yes.

8 MR. LIFLAND: Object to the
9 form of the question. Be sure
10 that you wait for an objection
11 before you answer. Thanks.

12 It's okay. You can
13 continue.

14 BY MS. CONROY:

15 Q. The second bullet point is
16 that you have provided medical expertise
17 to the product managers. What's a
18 product manager?

19 A. Those would have been
20 individuals in the -- who were in
21 marketing, would be responsible for the
22 product from a marketing perspective.

23 Q. And is that -- is that term,
24 "product managers in the marketing

1 department," pretty general -- or pretty
2 much a standard term in the
3 pharmaceutical industry?

4 A. It's a term that I've heard,
5 but I don't know if it's widely used in
6 all companies or not. I've heard it at
7 other companies.

8 Q. Do you know, did J --
9 Johnson & Johnson or Janssen have product
10 managers within the marketing department?

11 A. I've heard of that title
12 used.

13 Q. And when you say provided
14 medical expertise, that would have been
15 medical expertise with respect to
16 anesthesiology?

17 A. It would have been medical
18 expertise around the local anesthetics
19 that they were marketing, to provide
20 information to them.

21 Q. What about internal
22 medicine?

23 A. If the questions came up.

24 Q. Then you have "developed

1 strategies for the launching of a new
2 local anesthetic."

3 Do you see that, the third
4 bullet point?

5 A. Yes.

6 Q. That would have been
7 marketing strategies, correct?

8 A. No. That would have helped
9 them provide scientific and medical
10 information so that they would ensure
11 that the information in there was
12 medically accurate.

13 I'm not a marketing person,
14 so I would not have developed marketing
15 strategies.

16 Q. But medically accurate for
17 their marketing strategy, correct?

18 A. The information that was
19 included, we wanted to make sure it was
20 medically accurate. That was my role.

21 Q. And how would you -- how did
22 you perform that role?

23 A. So if questions came up
24 about, is this correct to say medically,

1 is this medically accurate, then I would
2 review that and answer it.

3 Q. Did you -- did you review
4 all of the marketing for the new local
5 anesthetic for medical accuracy?

6 A. Excuse me. I don't recall.

7 Q. Did you review some of it?

8 A. I would have reviewed it if
9 I was asked to review it. I was not part
10 of a group, per se, that reviewed it on
11 an ongoing basis. This would have been
12 as asked.

13 Q. Later at Janssen did you
14 review any marketing material for medical
15 or scientific accuracy?

16 A. Yes.

17 Q. And was it similar to, at
18 Astra, that -- if you were asked to do
19 so, or did you have more direct
20 responsibility?

21 A. At Janssen I had more direct
22 responsibility.

23 Q. So, but you didn't need to
24 just be asked to do it, it was something

1 that you would oversee generally?

2 A. When I served on the
3 promotional review committee, that would
4 have been my -- part of my
5 responsibilities at Janssen.

6 Q. Was there a promotional
7 review committee, if you recall, at
8 Astra?

9 A. I don't recall.

10 Q. And then your final bullet
11 point under marketing is "prepared
12 training modules for sales
13 representatives."

14 A training module is to help
15 to prepare sales representatives for
16 going out into the field and speaking to
17 clinicians; is that correct?

18 A. A training module would have
19 contained scientific information about
20 the compound that would have been -- that
21 could have been used to educate a sales
22 representative.

23 Q. And what would you do to
24 prepare a training module?

1 Let me ask it this way.

2 Would you have actually been preparing
3 the training module, or would you have
4 been asked to participate and prepare
5 sections of a training module?

6 A. I don't recall.

7 Q. Did you ever actually train
8 sales representatives at Astra by
9 speaking with them or preparing a video
10 or something like that, other than --
11 other than a written training module?

12 A. I don't recall.

13 Q. Are training modules
14 written, or were they at Astra?

15 A. In those days I believe it
16 would have been written.

17 Q. Have you ever done any sort
18 of video or web-based training for sales
19 representatives at any time in your
20 career?

21 A. I might have. I don't
22 recall.

23 Q. What about preparing or
24 assisting in the creation or editing of

1 the written training module? Have you
2 ever done that in your career other than
3 what you've referenced here at Astra?

4 A. Could you explain your
5 question again a little more?

6 Q. Sure. Did you ever -- did
7 you ever prepare training modules for
8 sales representatives at Johnson &
9 Johnson?

10 A. I don't recall preparing
11 them. I may have reviewed them. I think
12 that was part of your question.

13 Q. Okay. And did you review
14 them as part of the promotional review
15 committee at Johnson & Johnson or was it
16 separate from that?

17 A. I would have reviewed those
18 materials as part of the activities at
19 Johnson & Johnson.

20 Q. And at the promotional
21 review committee or elsewhere?

22 A. At the promotional review
23 committee.

24 Q. Was that the only time, at

1 the promotional review committee?

2 A. Materials would have gone
3 through some -- a promotional review
4 committee for review.

5 Q. And that's why you would see
6 them?

7 A. Yes.

8 Q. Okay. Under medical
9 information, the third bullet point, it
10 says, "Provided medical and anesthesia
11 expertise to product surveillance
12 coordinators and to pharmacists at an
13 offsite location, product safety."

14 Do you see that?

15 A. Yes, I do.

16 Q. What's a product
17 surveillance coordinator?

18 A. Astra had individuals who
19 would, when information came into the
20 company, would review adverse events and
21 sometimes they had required expertise on
22 local anesthetics to base -- to be able
23 to put together narratives that they
24 would submit to the FDA. They may have

1 wanted someone with clinical background
2 to help. That's what a product
3 surveillance -- it's a safety reporting
4 individual.

5 THE VIDEOGRAPHER: Raise the
6 bottom of the page.

7 MS. CONROY: Oh. Thanks.

8 BY MS. CONROY:

9 Q. And when you say expertise
10 to product surveillance coordinators, and
11 to pharmacists. Were the pharmacists
12 part of the Astra safety reporting, or
13 was that different?

14 A. Yes. Many of those
15 individuals were -- were trained as
16 pharmacists. And they also had contract
17 pharmacists working offsite as well who
18 answered questions and took in
19 information about adverse events.

20 Q. And the offsite location,
21 was that -- product safety was located
22 offsite?

23 A. They contracted with a
24 company that did -- received calls from

1 either -- I believe from consumers or
2 healthcare professionals about adverse
3 events. So was not physically on site at
4 the company. It was another company.

5 Q. So that, that offsite
6 company that dealt with product safety,
7 had both pharmacists and product
8 surveillance coordinators?

9 A. I believe that they -- some
10 of the product surveillance coordinators
11 had a pharmacy background. But I don't
12 know that for a fact.

13 But we provide -- if there
14 were questions about local anesthetics
15 specifically that the company felt needed
16 my input, then as a consultant I would
17 answer those questions.

18 Q. Okay. And then in March of
19 1997 you went to Parexel?

20 A. Yes.

21 Q. That's the name of the
22 company. It's located in Waltham, is on
23 Page 345. It's just at the very bottom.
24 And if you turn that page to Page 346.

1 It shows that you were the
2 associate medical director from March of
3 1997, when you left Astra, for about six
4 months, until September 1997. Then you
5 became the medical director of worldwide
6 medical affairs for two years. And then
7 senior medical director of North American
8 medical affairs from January of 2000, for
9 about nine months, until September,
10 correct?

11 A. Yes.

12 Q. And what kind of business
13 was --

14 A. The dates are approximate,
15 just to make sure.

16 Q. That's fine.

17 What kind of business was
18 Parexel?

19 A. Parexel is a contract
20 research organization.

21 Q. What does that mean?

22 A. Contract research
23 organizations are companies that provide
24 support to the pharmaceutical industry.

1 They may provide support to help them
2 develop their clinical drugs, as part of
3 helping with clinical trial design and
4 implementation, safety reporting. They
5 may provide statistical and regulatory
6 support that would be contracted with a
7 pharmaceutical company for those types of
8 activities.

9 Q. Did they provide
10 investigators?

11 A. If a company requested that
12 a contract research organization try and
13 identify investigators for a clinical
14 trial, then a contract research
15 organization might go out and do a site
16 investigation, to reach out to certain
17 investigators to see if there's interest
18 in participating in a study. Those are
19 some of the activities, not all that a
20 contract research organization would do.

21 Q. And would this -- would --
22 was Parexel involved in -- let me ask.
23 Were you involved, while you were at
24 Parexel, in clinical trials before a

1 product went on the market?

2 A. Yes.

3 Q. And were you also -- was
4 Parexel and your responsibilities at
5 Parexel concerning postmarketing studies?

6 A. I don't recall if we did
7 post -- if I was involved in
8 postmarketing studies when I was at
9 Parexel.

10 Q. Did Parexel participate in
11 postmarketing studies?

12 A. I believe that those
13 activities would be part of the
14 activities that they could provide to a
15 pharmaceutical company, if such a request
16 was made.

17 Q. And while at Parexel, you
18 worked -- I'm looking at R&D, research
19 and development. You were involved with
20 clinical trials for several
21 cardiovascular drugs. Do you see that?

22 A. I'm sorry, where are you
23 looking?

24 Q. I'm right under R&D. And

1 then it says clinical trials experience.
2 And your first bullet point says that you
3 were the medical and safety monitor for
4 Phase II-B and III clinical trials?

5 A. Yes.

6 Q. Phase -- those are Phase II
7 and Phase III trials?

8 A. Correct. Yes, that's
9 correct.

10 Q. What kind of cardiovascular
11 drugs?

12 A. The drug was a beta blocker,
13 I believe it was carvedilol.

14 Q. Okay. And who manufactured
15 that drug?

16 A. I don't remember who
17 manufactured it.

18 Q. You would have been doing --
19 Parexel did not manufacture any drugs,
20 correct?

21 A. That's correct. There
22 was -- these were activities that were
23 done for a pharmaceutical company.

24 Q. Okay. Did you do any work

1 for Astra -- did Parexel do any work for
2 Astra?

3 A. I personally was not
4 involved in any activities doing work for
5 Astra when I was at Parexel to the best
6 of my recollection.

7 Q. Do you recall if you did any
8 work for Johnson & Johnson or Janssen?

9 A. I do recall doing some work
10 for Janssen at the time.

11 Q. Okay. And what -- what kind
12 of products did you do work on for
13 Janssen while you were at Parexel?

14 A. Janssen was developing a
15 product which was designed to be used to
16 treat postoperative pain. And I was
17 involved as a Parexel employee working on
18 those programs for Janssen.

19 Q. And was that product
20 approved by the FDA or was it -- or were
21 they seeking to get it approved?

22 A. The product was in
23 development.

24 Q. And do you know if it was

1 ever approved?

2 A. To the best of my knowledge
3 it has not. But I'm not -- I'm not sure.

4 Q. Was it an opioid?

5 A. It was a system that was
6 designed to administer an opioid pain
7 medication to patients who had undergone
8 surgery. It was post -- used for
9 postoperative pain.

10 Q. Was it a device?

11 A. Yes.

12 Q. So I'm still on that first
13 bullet point. At the very end of the
14 bullet point it says "and several pain
15 control products."

16 Would you have considered
17 that device a pain control product?

18 A. Yes.

19 Q. What other pain control
20 products were you involved in at Parexel?

21 A. Part of my activities at
22 Parexel was I served as an -- in a
23 consulting role as a Parexel employee to
24 a number of companies that made -- were

1 developing pain products. So they would
2 have come to me as part of those
3 activities.

4 Q. Any opioid drugs?

5 A. Yes.

6 Q. And what were they?

7 A. I think there was some work
8 for oxycodone, as I recall. But I don't
9 remember. Some of the other companies,
10 but I don't remember specifics.

11 Q. Did you do any consulting
12 work at Parexel for Purdue Pharma?

13 A. Yes. They reached out to me
14 on one occasion to do some work with
15 them.

16 Q. And do you recall what that
17 was, what that work was?

18 A. It was one single project,
19 and I don't remember what the nature of
20 the project was.

21 Q. It would -- it would have
22 involved an opioid though, correct?

23 A. Correct.

24 Q. What about Endo?

1 A. I don't recall if it was
2 Endo or not.

3 Q. Okay. Mallinckrodt, do you
4 recall if you did any --

5 A. No, I don't recall any work
6 from Mallinckrodt. There were some other
7 opioid analgesics. I believe those were
8 predominately pills. But again, I don't
9 remember the specifics on which companies
10 had come -- had come to me.

11 Q. OxyContin was on the market
12 at this time?

13 A. I don't remember. I don't
14 recall if this was immediate-release
15 oxycodone or for a controlled-release
16 oxycodone that they came to me for.

17 Q. Okay. Do you recall the
18 nature of the consulting work for Purdue
19 Pharma? Would it -- would it have
20 involved a clinical trial or some type of
21 safety monitoring, or do you remember
22 what it was?

23 A. I don't remember the
24 specifics.

1 Q. Was that the first time that
2 you had worked -- strike that.

3 Had you worked with a
4 controlled-release Oxycodone product
5 prior to the project that Purdue Pharma
6 brought to Parexel?

7 A. So to be clear, I wasn't --
8 I didn't recall whether it was an
9 immediate release or controlled-release.

10 Q. I see.

11 A. Right.

12 Q. Do you recall if you worked
13 on a controlled-release opioid regardless
14 of the manufacturer while you were at
15 Parexel?

16 A. I don't recall having those
17 activities while I was at Parexel.

18 Q. What other pharmaceutical
19 companies do you recall working with that
20 had pain medications or devices while you
21 were at Parexel?

22 A. I don't recall.

23 Q. Okay. You have -- the
24 second bullet point, product -- I'm

1 sorry -- "protocol development and
2 implementation."

3 Was that protocol
4 development for clinical trials for
5 developing products or for postmarket?

6 A. The protocol development and
7 implementation would have been for --
8 well one thing that comes to mind is the
9 device for Janssen that I worked with the
10 people at Janssen on that. There may
11 have been others as well.

12 Q. The next bullet point you
13 have "medical and scientific input and
14 review into statistical analysis plans as
15 well as the preparation of ISS/ISE
16 documents."

17 A. Yes.

18 Q. What are those, ISS/ISE
19 documents?

20 A. ISS is integrated summary of
21 safety. And ISE is integrated summary of
22 efficacy documents.

23 Q. And who are those being
24 prepared for?

1 A. A number of different
2 pharmaceutical companies. I don't have
3 the specifics as to which companies it
4 would have been.

5 Q. And what would -- would
6 those summaries be used for by the
7 companies?

8 A. As part of a submission to
9 FDA.

10 Q. As part of a new drug
11 application?

12 A. Yes.

13 Q. Then you have extensive
14 clinical trials experience in the areas
15 of acute and chronic pain. Is that also
16 in relation to the Janssen device?

17 A. Yes.

18 Q. Any other products that you
19 recall clinical trial experience?

20 A. Not that come to mind
21 immediately.

22 Q. Can you -- can you describe
23 for me what some of those clinical
24 trials -- what they were for the delivery

1 system, for the Janssen delivery system?

2 A. The -- prescribe it -- how
3 to use the system in various patient
4 populations for postoperative pain. It
5 may have been individuals undergoing
6 different types of surgeries.

7 Q. Did you secure investigators
8 for them?

9 A. I don't recall that as a
10 function that I might have performed for
11 Janssen.

12 Q. Do you recall where any of
13 those patient populations were located
14 for those clinical trials?

15 A. Those were studies that
16 would have been conducted in the U.S. So
17 they would have been U.S. patients.

18 Q. Did you do site visits, do
19 you recall, for those?

20 A. I don't recall.

21 Q. Do you recall how many
22 patients might have been involved in any
23 of those clinical trials?

24 A. I don't have the exact

1 numbers. I'd have to look at
2 documentation to see the protocols to
3 understand the proposed number and how
4 many were actually incorporated.

5 Q. Were those clinical trials
6 actually carried out?

7 A. I believe so.

8 Q. Did you ever appear as one
9 of the investigators on any of those
10 clinical trials?

11 A. I'm sorry, I didn't
12 understand the question. Could you
13 repeat your question?

14 Q. Sure. When you were
15 involved in the extensive clinical trials
16 experience in the areas of acute and
17 chronic pain --

18 A. Right.

19 Q. -- would you yourself have
20 been listed as one of the investigators?

21 A. No, I would not have been an
22 investigator. But I would have been
23 involved in developing the protocols,
24 working to understand the patient --

1 appropriate patient population, executing
2 the studies, obtaining information on
3 adverse event reporting, reviewing that,
4 all the clinical -- medical monitoring
5 that goes along with clinical studies.

6 So from the initiation of
7 protocol development all the way through
8 to study completion and involved in
9 preparing some of the documents, working
10 with companies to submit those to the
11 FDA. I would have been involved in those
12 aspects.

13 Q. And so you would have been
14 involved in potentially writing up what
15 had occurred at the clinical trial,
16 including adverse event reports and the
17 safety and efficacy results, if that was
18 what the trial encompassed?

19 A. Depending on what the
20 company contracted with the CRO to do, I
21 certainly had those capabilities and
22 could do that.

23 Q. And what does a CRO stand
24 for?

1 A. Contract research
2 organization.

3 Q. And that's what Parexel was,
4 the contract --

5 A. Yeah.

6 Q. -- resource organization?

7 A. Yes.

8 THE WITNESS: Can I take a
9 break?

10 MS. CONROY: Of course you
11 can. Yes.

12 THE VIDEOGRAPHER: All
13 right. Stand by, please. The
14 time is 10:39 a.m. Going off the
15 record.

16 (Short break.)

17 THE VIDEOGRAPHER: We are
18 back on the record. The time is
19 10:53 a.m.

20 BY MS. CONROY:

21 Q. Doctor, during the break
22 your counsel told me that you wanted to
23 clarify an answer --

24 A. Yes.

1 Q. -- from this morning?

2 A. That's right.

3 Q. What was that?

4 A. We were talking earlier
5 about postmarketing studies and I wanted
6 to clarify the conversation to make sure
7 we were talking about studies such as
8 investigator-initiated studies, those
9 type of postmarketing studies.

10 The companies themselves
11 engage in postmarketing clinical trials,
12 postmarketing studies. And the
13 company-sponsored studies that are
14 postmarketing studies, the company is
15 involved in writing the protocol and
16 developing it. So I wanted to make sure
17 that that distinction was clear between
18 two types of postmarketing studies. They
19 may be controlled clinical trials that
20 are done by the company as postmarketing
21 studies or they may be
22 investigator-initiated studies.

23 And the point I was making
24 about the investigator-initiated studies

1 are, with time, the companies had come to
2 a process where the involvement of the
3 company, for the investigator-initiated
4 studies, had become less.

5 Q. So a controlled clinical
6 trial that was sponsored by the company,
7 the protocol would be developed by the
8 company?

9 A. Yes.

10 Q. And you were -- what -- you
11 were talking about it earlier, the
12 investigator-initiated study, that would
13 be a postmarketing study in a study that
14 was -- that study would still be paid for
15 by the company, correct?

16 A. The company would, yes.
17 Depending on the arrangement with the
18 investigator, a company may pay for that
19 study, correct.

20 Q. But the investigator would
21 develop the protocol?

22 A. Yes.

23 Q. The protocol would be
24 reviewed by the company?

1 A. Yes. And we talked about
2 that change at the time.

3 Q. Okay.

4 A. So I just wanted to make
5 sure that that was clear.

6 Q. Doctor, do you recall
7 working with Dr. Reder, R-E-D-E-R, or
8 Dr. Kaiko, K-A-I-K-O, from Purdue Pharma?

9 A. I remember those names. And
10 I think that I may have been involved
11 with Dr. Kaiko. Around -- when I talked
12 to you about the Purdue consulting
13 activity that I did, Parexel, that is a
14 name that comes to mind. But I had also
15 indicated that I didn't recall exactly
16 the nature of the formulation or the
17 nature of the activity.

18 Q. Do you recall a woman named
19 Lee Ann Storey?

20 A. Yes, I believe Lee Ann
21 Storey was a -- is a medical writer I
22 believe.

23 Q. Okay. Do you know who --
24 who her employer is or was?

1 A. I don't recall if she was a
2 medical writer for -- no, I don't recall
3 what her -- to answer your question, I
4 don't remember who her -- who her
5 employer was.

6 Q. What's a medical writer?

7 A. A medical writer is an
8 individual who -- who may be contracted
9 to do a variety of activities, either for
10 a pharmaceutical company or a contract
11 research organization, to write
12 protocols, study of reports, et cetera.

13 Q. Do you have any memory of
14 her working either at or for -- or for
15 Purdue Pharma?

16 A. I don't recall which company
17 she worked at. I recall having some
18 interaction with her, but I don't
19 remember which company she worked at at
20 the time when I had that -- when I had
21 that interaction.

22 Q. Do you recall your
23 interaction with Dr. Kaiko?

24 A. Not clearly, no.

1 Q. Have -- did you ever meet
2 him face-to-face?

3 A. I might have, but I'm not
4 certain.

5 Q. Do you recall if your
6 involvement with Dr. Kaiko extended after
7 Parexel?

8 A. I don't have a recollection
9 of that.

10 Q. Do you recall ever doing
11 tests on Oxycodone hydrochloride with
12 respect to blood plasma levels?

13 A. I'm not sure I understand
14 the question.

15 Q. Do you recall ever doing
16 tests while you were at Parexel or
17 overseeing tests or clinical trials with
18 respect to plasma levels of Oxycodone?

19 A. I would not have been
20 providing oversight to those types of
21 activities for Purdue Pharma.

22 The study report that I
23 talked to you about, it may have provided
24 that type of information, but again I

1 don't recall the nature of the study
2 report. But I would not have done those
3 type of studies and provided those type
4 of support activities to Purdue looking
5 at those types of levels.

6 Q. When you say you wouldn't
7 have -- have done those types of studies
8 or support activities, what would you
9 have done for Purdue?

10 A. So if Purdue provided me
11 with the data and wanted me to review it,
12 and depending on what they wanted to do
13 with the information. So for example, if
14 they were going to go for a regulatory
15 claim, they may have asked me to review
16 it and see what I thought about the
17 information clinically. But I would not
18 have been the person engaged in
19 conducting those studies.

20 Q. And what would have been the
21 purpose for you to review the -- the data
22 from such studies?

23 A. While I was at Parexel?

24 Q. Correct.

1 A. If they were interested in
2 doing regulatory submission for one of
3 their compounds, they may have gone to me
4 based on my background and expertise to
5 look at the data to see, was it, you
6 know, clinically -- did it make sense
7 clinically, and what -- that type of a
8 thing. So that -- that's how I would do
9 it. It would be review data that they
10 would have provided to me.

11 Q. And would you have reviewed
12 that data for safety and/or efficacy?

13 A. If I was asked to do so.

14 Q. And what would the -- what
15 would the result be, a report that you
16 would send back to Purdue Pharma or
17 what -- what would -- what would you
18 actually do? What would your work be?

19 A. Depending on what they
20 contracted me to do. They may ask me to
21 review it to see if the various elements
22 that might be of interest to a regulatory
23 body were contained in there. Whether --
24 what types of additional studies might be

1 needed to have a more robust submission
2 to a regulatory authority.

3 It would really be depending
4 on what they had contracted me to ask --
5 you know, what the services they wanted
6 me to provide.

7 Q. And I think you're
8 explaining the range of services. But
9 what would be -- the range of services
10 would typically be, you would review the
11 data and then you may, in fact, give your
12 opinion as to the sufficiency of the data
13 for a regulatory finding?

14 A. That could be one activity,
15 yes.

16 Q. Would you have ever -- would
17 you -- strike that.

18 Is it possible that you
19 would have been asked by Purdue to assist
20 in the creation of protocols for such
21 clinical trials?

22 MR. LIFLAND: Object to the
23 form of the question.

24 THE WITNESS: Let me --

1 could you repeat the question for
2 me, please?

3 BY MS. CONROY:

4 Q. Sure.

5 Could you have been asked by
6 Purdue to assist in the creation of
7 protocols for such clinical trials? I'm
8 talking about the clinical trials to make
9 some sort of a regulatory submission.

10 MR. LIFLAND: Same
11 objection. You can answer.

12 THE WITNESS: Typically I
13 think the structure of Purdue is
14 they have their own -- they have
15 their own experts doing those
16 types of activities.

17 And I don't recall reviewing
18 the protocol, per se. And I -- I
19 certainly don't recall them coming
20 to me to develop a protocol from
21 the very beginning.

22 I might have been asked to
23 review a protocol, but I -- as I
24 said, they had their own inhouse

1 experts who may have written their
2 own protocols or gone to other
3 people to write them.

4 BY MS. CONROY:

5 Q. How do you know that they
6 had their own experts at Purdue?

7 A. Because there were people at
8 the company who have background and
9 expertise in pain medicine.

10 Q. Do you know who -- who those
11 individuals were?

12 A. Well, I -- I -- there were
13 people that worked at Purdue. I don't
14 know if they were in the protocol
15 development department. But it was a
16 pain analgesia company.

17 Q. Who did you know there?

18 A. I had an opportunity to
19 interact with Dr. David Haddox.

20 Q. And how -- on what occasions
21 did you interact with Dr. David Haddox,
22 H-A-D-D-O-X?

23 A. Through the activities
24 predominately through RADARS.

1 But I -- again, I don't know
2 whether Dr. Haddox was involved in
3 developing the protocols or not. I don't
4 know that.

5 Q. Okay. Who else did you know
6 at Purdue?

7 A. There was another person
8 that I don't recall his name. He was in
9 their epidemiology group, but I don't
10 recall his name.

11 Q. And you know Dr. Kaiko?

12 A. I knew of Dr. Kaiko, yes.
13 But Dr. Kaiko was -- again, there might
14 have been another person.

15 Q. Did you know Dr. Reder?

16 A. I had met Dr. Reder and
17 spoken with him a few times. I did not
18 know him well.

19 Q. Did you ever meet Dr. Haddox
20 or Dr. Reder at any American Pain Society
21 meeting or American Pain Foundation
22 meetings?

23 A. I don't recall. I did
24 poster presentations as part of, again,

1 scientific activities. People would have
2 come up to me and asked me questions
3 about the scientific data that I was
4 presenting. I don't remember everyone
5 who would have come to talk to me. So
6 it's possible that they might have. But
7 it doesn't come to mind specifically
8 talking about that.

9 Q. So you don't recall anyone
10 from Purdue Pharma ever speaking to you
11 at any of -- at any of your poster
12 presentations or any of the other --

13 A. No. I'm sorry. I thought
14 the question was do I remember having
15 specific conversations with those
16 individuals at the American Pain Society.
17 And I don't.

18 There may have been people
19 from Purdue Pharma who would have come as
20 a matter of being individuals
21 participating in the meeting who have
22 come by to speak -- to look at it.

23 They may or may not have had
24 badges indicating what their -- what

1 companies they worked with.

2 So there may have been, but
3 I can't -- I don't -- I can't at this
4 point recollect a specific individual who
5 I might have had a discussion with. It's
6 certainly possible.

7 Q. Do you have a recollection
8 of knowing that someone from Purdue was
9 asking you questions about a particular
10 poster or findings of your own?

11 A. There may have been somebody
12 from -- and I don't remember the name of
13 the person, scientist, who had questions
14 about some of the work that we had done.
15 But I -- that may have been -- that is
16 one that comes to mind. But I don't
17 recall if there are others, no.

18 Q. What about any individuals
19 from Mallinckrodt? Do you recall
20 Mallinckrodt employees asking you any
21 questions or speaking to you at any of
22 your poster presentations?

23 A. Not specifically individuals
24 from Mallinckrodt.

1 Q. Did you -- do you recall any
2 other instances when you would have had
3 conversations with individuals from
4 Mallinckrodt at any time during your
5 career?

6 A. If they were participants of
7 some of the surveillance programs that we
8 had, such as RADARS, then they may have.
9 And I don't know whether Mallinckrodt was
10 a participant of RADARS or not. But that
11 might have been a place.

12 I also served on the ACTION
13 group. ACTION was a group of
14 individuals which was comprised of people
15 from the FDA, from industry, and from
16 academia. And companies -- certain
17 companies provided representatives to
18 ACTION. I was one of the people from
19 Janssen. There were -- from -- from
20 Janssen. There were other Janssen people
21 who were there at other points in time.
22 And I might have spoken to somebody from
23 -- either from Mallinckrodt or from
24 Purdue at those meetings.

1 Q. Is ACTION A-C-T-I-O-N?

2 A. I always get the spelling
3 wrong. I have to look it up. I think
4 it's -- so --

5 Q. Well, let me ask it. Is it
6 an acronym?

7 A. It is, yes. It's not
8 A-C-T-I-O-N.

9 Q. What other companies are you
10 aware of today that manufactured and sold
11 opioids in the United States for chronic
12 pain?

13 A. Endo Pharmaceuticals, Purdue
14 Pharma, Janssen, Mallinckrodt. I'm sure
15 there may be others that I'm not
16 remembering. Cephalon I believe.

17 Q. Are you familiar with
18 Actavis? Actavis, the name of that
19 company?

20 A. I'm not familiar with that
21 company.

22 Q. Watson? Are you familiar
23 with that?

24 A. Yes, I've heard of Watson.

1 Q. Do you know if they
2 manufactured an opioid product for pain?

3 A. I don't remember what
4 product they have.

5 Q. What about Rhodes
6 R-H-O-D-E-S, a Rhodes Technologies?

7 A. I'm not familiar with the
8 company.

9 Q. Do you recall having any
10 involvement with respect to Oxycodone and
11 bioequivalence testing with morphine
12 while you were at Parexel?

13 A. Could you clarify that
14 question for me?

15 Q. Probably not. So you know,
16 I'm -- what I'm asking is, do you have
17 any memory of having any involvement at
18 all while you were at Parexel with
19 evaluating or supervising or studying or
20 having your hands on anywhere
21 bioequivalency data with respect to
22 comparisons between oxycodone and
23 morphine or MS Contin or some type of
24 morphine drug?

1 A. There was work that I had
2 done as part of a consulting activity
3 with Purdue. And I don't remember the
4 nature of the work and whether there were
5 data that I might have looked at that
6 addressed that question.

7 But I did not perform or
8 oversee those types of -- that type of
9 work to acquire that data. But it may
10 have been data that I reviewed, but I
11 simply don't remember.

12 Q. So you don't remember
13 whether or not you -- you don't remember
14 what the purpose of the review of any of
15 that data might have been?

16 A. I don't.

17 Q. Okay. But you do recall
18 that you looked at bioequivalency data?

19 A. No, I don't remember the
20 nature of the data. So I don't know if I
21 looked at bioequivalency data or not.

22 Q. If I wanted to know what
23 involvement you had at Parexel with
24 respect to Purdue products, who would

1 know that?

2 A. I think you would need to
3 reach out to Parexel to see the
4 consulting agreement that was done for
5 one specific activity that I had and
6 describing that and then go from there.

7 Q. Parexel is still in
8 business?

9 A. Yes.

10 Q. And do you have any
11 involvement with Parexel? Do you know
12 anybody there anymore?

13 A. No.

14 Q. Are they still in Waltham?
15 Do you know?

16 A. I believe so.

17 Q. Do you -- did you ever
18 use -- did you ever use Parexel when you
19 were at Janssen?

20 A. I recall that we were
21 looking to do some work and had a number
22 of different companies to bid on the
23 work. And Parexel was one of the
24 companies that came by to bid on it. But

1 I think we went with a different company.
2 So I don't recall any
3 specific activities with Parexel. There
4 may have been small projects that we had
5 done with them. But I don't recall that.
6 And it doesn't jump to mind.

7 Q. Why did you leave Astra and
8 go to Parexel?

9 A. I left Astra to go to
10 Parexel. I was a consult -- I was an
11 advisor at Astra. And I really wanted to
12 learn the clinical trials business. And
13 I think the best way to do that is to go
14 and really learn about the pharmaceutical
15 industry, to go to a contract research
16 organization. Because there I gained
17 expertise in protocol design, protocol
18 execution, implementation, a lot of
19 information on looking at how you do
20 medical monitoring, which was a big role
21 for me and many of the medical physicians
22 working at contract research
23 organizations, analyzing data, analyzing
24 adverse events, so really the full

1 breadth of activity that take place for
2 clinical trials.

3 And I believe one of the
4 best places to do that is a contract
5 research organization.

6 Q. However, the contract
7 research organization does not actually
8 conduct the clinical trial, correct?

9 A. They can. Sometimes they
10 can, yes.

11 Q. Were --

12 A. Yes.

13 Q. So were you involved in that
14 as well? Were you ever a participant --
15 you know, involved in the actual clinical
16 trial?

17 A. So I would ask to clarify
18 what you mean by involved in a clinical
19 trial?

20 Q. I don't mean as a subject.

21 A. No, I -- no, I understand.

22 Do you mean that I write --
23 so I can clarify, you mean did I write
24 protocols, develop them, interact with

1 clinical sites, and then when the data
2 came in, analyze the data, looked at it,
3 helped to review study reports that may
4 have been written by medical writers and
5 then work with all those -- those type of
6 activities?

7 Q. Those are all things that
8 you did, correct?

9 A. Yes, that's correct.

10 Q. What you did not do was you
11 were -- you never were at the clinical
12 site itself, you were never collecting
13 the data yourself from the patients or
14 the subjects in the clinical trial,
15 correct?

16 A. That would have been done at
17 the sites. I may have visited a clinical
18 site if there were concerns or issues
19 that I needed to speak to the
20 investigator on or if the investigator,
21 or their study coordinator -- a study
22 coordinator would be a person working
23 with the investigator on the study
24 execution. I would certainly answer

1 those questions.

2 But I did not work at a site
3 specifically to collect data from
4 patients.

5 Q. And why do you believe it's
6 better to gain an expertise at a clinical
7 research organization -- sorry, contract
8 resource organization rather than at an
9 actual pharmaceutical company?

10 A. Companies are a wonderful
11 place to do it. I think the breadth of
12 experience you get at a CRO would be
13 different because contract research
14 organizations work with a variety of
15 pharmaceutical companies. So you really
16 have an opportunity to see how different
17 companies perform clinical trials.

18 So if you work at one
19 company, you may have a wonderful
20 experience on how that company works.
21 But if you want to see in the industry to
22 see how different companies run their
23 trials, then I believe a CRO, contract
24 research organization, is an excellent

1 place to do that.

2 Q. So while you were at
3 Parexel, you would have had the
4 opportunity to gain insight into how
5 Purdue Pharma conducted clinical trials?

6 A. If Purdue Pharma was a
7 company that was working with Parexel.

8 My interaction, as I've
9 already indicated, was just to provide
10 consulting work for a single project.
11 But for other companies where their
12 clinical programs might be run with a
13 company like Parexel, then one would have
14 had an opportunity to see the breadth of
15 clinical studies that they were putting
16 together, ultimately culminating in
17 regulatory submission for approval of the
18 product.

19 Q. Were there any companies
20 that you recall that did just that, what
21 you were explaining for acute and chronic
22 pain?

23 A. At Janssen.

24 Q. While you were at Parexel?

1 A. Yes.

2 Q. And so you were able to see
3 how Janssen conducted clinical trials?

4 A. Yes.

5 (Brief interruption.)

6 MS. CONROY: I think whoever
7 is on the phone needs to put it on
8 mute.

9 BY MS. CONROY:

10 Q. In 2000 you left Parexel and
11 went to Janssen, correct?

12 A. Yes.

13 Q. And why is that?

14 A. I had an opportunity -- I
15 had worked with Janssen on -- on their
16 clinical studies. I really liked the way
17 they conducted the -- the studies. And I
18 had an opportunity to join their medical
19 affairs group and work on pain relief and
20 compounds which, as an anesthesiologist,
21 was of great interest to me.

22 Q. And that's here on your CV,
23 October 2000 to March 2003. You went in
24 as the director of medical development

1 anesthesia -- analgesia and mycology?

2 A. Yes. I'm sorry.

3 Q. Page 344.

4 A. Thank you. Let me circle
5 back.

6 Excuse me.

7 Yes, the dates are
8 approximate, but the October 2000 date is
9 correct. The other -- the other date is
10 about when I had gone from being a
11 director to senior director are
12 approximate.

13 Q. Okay. And were you paid
14 more when you went to Janssen?

15 A. Yes, I was.

16 Q. And what was your -- what
17 was your pay structure, was there a base
18 salary?

19 A. My pay structure where?

20 Q. At Janssen.

21 A. Oh.

22 Q. When you went to Janssen.

23 A. Yes, I had a salary and
24 other compensation.

1 Q. What was your -- when you
2 started what was your other compensation,
3 just generally, you know, not --

4 A. I had a bonus. I think I
5 had stock options.

6 Q. What was the bonus based on?

7 A. It may have been related to
8 merit and performance I would think. It
9 should -- that's typically how those
10 bonuses were given out.

11 Q. Do you know if it was based
12 in any way on the performance of the
13 sales performance of any of the products
14 you were involved in?

15 A. I don't know. I don't know.
16 I -- I don't know. I always assumed it
17 was related to my work, but I don't know
18 that.

19 Q. Okay. You don't -- is it
20 fair to say you don't know because you
21 never asked?

22 A. Yes, that's fair to say I
23 don't know because I never asked.

24 Q. Okay. And did that

1 continue, that basic structure, base
2 salary, a bonus, and stock options, until
3 you left in 2015?

4 A. I left in 2017.

5 Q. I'm sorry, 2017?

6 A. Right. Yes.

7 Q. Did you become a shareholder
8 of Janssen when you were hired in October
9 of 2000 or was there some period of time
10 that you had to wait?

11 A. There was a vesting period.

12 Q. Do you recall what the
13 vesting period was?

14 A. I'm not exactly sure.

15 Q. Was it in -- was it months
16 or years?

17 A. It was years.

18 Q. But at some point you did
19 vest?

20 A. Yes.

21 Q. Okay. And were you
22 100 percent vested at some point?

23 A. Yes.

24 Q. Do you still own -- was it

1 Johnson & Johnson stock or Janssen stock,
2 or both, do you know?

3 A. Johnson & Johnson stock. I
4 own Johnson -- Johnson & Johnson stock,
5 yes.

6 Q. And do you still own it?

7 A. Yes.

8 Q. When you left in 2017, was
9 there any sort of severance agreement
10 with you?

11 A. I'm not sure exactly if I'm
12 in a position to answer that or not.

13 Q. Why is that?

14 MR. LIFLAND: Can we take a
15 break? I suspect he just has a
16 question about the extent that he
17 needs to get into personal
18 financial issues.

19 Maybe you can answer.

20 BY MS. CONROY:

21 Q. Is that your concern, that
22 I'm going to ask you about personal
23 financial concerns?

24 A. Yes.

1 Q. Okay. Let me just ask you a
2 few questions first about the actual
3 agreement.

4 Is there a severance
5 agreement --

6 A. Yes.

7 Q. -- with Johnson & Johnson?

8 A. I have one, yes.

9 Q. And is it still in effect?

10 A. No.

11 Q. How long did it last?

12 A. Eight months.

13 Q. And did it have a financial
14 component?

15 A. Yes.

16 Q. Do you receive any -- do you
17 receive any monies from Janssen or
18 Johnson & Johnson today as a result of
19 that severance agreement?

20 A. I do not.

21 Q. Are you being paid today by
22 anybody?

23 A. No, I'm not.

24 Q. So you -- you are not being

1 paid for your time?

2 A. I am not.

3 Q. Were you paid or do you
4 expect to be paid for your time in
5 preparing for this deposition?

6 A. No, I -- I do not. And I
7 have not been.

8 Q. What about your expenses to
9 drive here, drive home, that sort of
10 thing?

11 A. No.

12 Q. Is your appearance here
13 today as a result of the severance
14 agreement?

15 A. No, it's not related at all.

16 Q. Why are you here?

17 A. Because I was supposed.

18 MR. LIFLAND: I suspect you
19 meant to say subpoenaed?

20 THE WITNESS: Subpoenaed.

21 BY MS. CONROY:

22 Q. Were you subpoenaed?

23 MR. LIFLAND: A request was
24 made. It was Exhibit 1.

1 THE WITNESS: Yes.

2 BY MS. CONROY:

3 Q. What do you understand this
4 lawsuit to be about?

5 A. There are a number --

6 MR. LIFLAND: I would -- I
7 would just caution you to answer
8 only based on your knowledge
9 independent of your conversations
10 from counsel.

11 THE WITNESS: Understood.

12 I don't know very much about
13 the lawsuit. I understand there
14 were a number of companies that
15 were -- were lawsuit engaged for
16 activities around opioid related,
17 but I don't know the specifics of
18 the lawsuit.

19 BY MS. CONROY:

20 Q. What do you know about it
21 generally?

22 A. There were a number of
23 companies, as I said, that were -- that
24 are manufacturers and distribute opioid

1 analgesics, and there are a number of
2 different area -- different groups of
3 people who were suing them, and so
4 this -- this is kind of a conglomerate of
5 that, of activities.

6 Q. And do you have an
7 understanding of who it is who is suing
8 the manufacturers and the wholesalers?

9 A. No, not exactly.

10 Q. Any idea at all?

11 A. No, not really.

12 Q. Have you ever seen the
13 complaint?

14 Do you know what that is?
15 Have you ever heard that word, complaint?

16 A. Yes, I do. I saw part of
17 the complaint, but I didn't go through it
18 in great detail.

19 Q. Okay. What did you see of
20 it, what part of it did you see?

21 A. Just some of the -- just the
22 number of companies that were involved.
23 I got to see that. And some of the
24 things that were listed about it. But I

1 did not go into -- I did not go through
2 it in detail.

3 Q. Okay. You didn't look at
4 who it was that was suing?

5 A. No, I did not.

6 Q. Do you know whether it's an
7 individual that's suing?

8 A. I think it's a group of
9 individuals -- I think it's a group of
10 interested parties that are suing. But I
11 don't know who those parties are.

12 Q. Do you know why they are
13 interested? Do you know why they are
14 interested parties?

15 A. I think there's concern that
16 there may -- that they are alleging that
17 there may have been wrongdoing in terms
18 of the activities related to the
19 marketing of these products and there
20 were damages related to that.

21 Q. Do you know how the parties
22 that are suing have been damaged?

23 A. I think -- well, I think it
24 was alleged that there was inappropriate

1 prescribing or inappropriate marketing,
2 things that may have led to people
3 getting -- getting medications where they
4 should not have or maybe given a false
5 sense of security of those medications,
6 and that led to people becoming addicted
7 to those medications.

8 Q. Do you think it's addicted
9 individuals that are suing?

10 MR. LIFLAND: Object to the
11 form of the question.

12 THE WITNESS: No, I think --
13 I think there are groups of
14 individuals who are represented
15 who are concerned about people
16 that their -- either where they
17 live -- again, I don't -- what I
18 hope you're hearing is, I don't
19 really have a lot of knowledge
20 about this. That's my -- that's
21 kind of what I'm saying.

22 BY MS. CONROY:

23 Q. Have you read about this
24 lawsuit in the media?

1 A. No, I have not.

2 Q. So you haven't heard about
3 it in the media, you've --

4 A. I have --

5 Q. -- you only heard about it
6 from the contact about this deposition?

7 A. I -- yes.

8 Q. Do you know where the
9 lawsuit is pending? Do you know what
10 court it's in?

11 A. I don't.

12 Q. What do you understand
13 was -- are the allegations with respect
14 to the marketing of the products?

15 MR. LIFLAND: Object to the
16 form of the question.

17 THE WITNESS: I'm sorry, I
18 didn't hear.

19 MR. LIFLAND: I -- I just
20 objected. You can answer.

21 THE WITNESS: Oh.

22 I only -- my understanding
23 is that there may have been
24 inappropriate marketing, that's

1 all I know.

2 BY MS. CONROY:

3 Q. Have you ever heard in the
4 past that there was inappropriate
5 marketing for example, of OxyContin by
6 Purdue Pharma?

7 A. I've heard of that, that
8 allegation in the media.

9 Q. Did -- were you aware that
10 they pled guilty to inappropriate
11 marketing?

12 A. I had heard that.

13 Q. When did you hear that?

14 A. Sometime ago, I don't
15 remember the exact date.

16 Q. Did you -- did you have, at
17 any time -- I'm not going to ask you if
18 you remember specifically now, but did
19 you at some point understand what -- why
20 Purdue Pharma pled guilty?

21 A. No, I don't have the
22 specifics of the background that would
23 have led them to do that.

24 Q. So you never looked into

1 that?

2 A. I did not.

3 Q. Okay. Do you know if
4 Janssen has ever been under any
5 investigation with respect to its
6 marketing of opioid analgesics?

7 A. Not that I'm aware of.

8 Q. Okay. You never heard that?

9 A. Not that I've heard that
10 there was an investigation.

11 Q. Have you heard about any
12 sort of investigation or activity with
13 respect to Janssen's marketing of
14 opioids?

15 A. Not that I'm -- no, I'm not
16 aware of an investigation in terms of the
17 marketing of their opioids.

18 Q. When you -- what do you mean
19 when you use the term "investigation"?

20 A. That's what -- I thought
21 that's what you had asked me.

22 Q. I'm asking you, what -- when
23 you answered me and said, "I'm not aware
24 of any investigation," what do -- are you

1 being specific about a criminal
2 investigation versus --

3 A. No.

4 Q. -- something else --

5 A. No.

6 Q. -- or just any -- you are
7 just talking about any kind of
8 investigation at all?

9 A. Correct. Correct.

10 Q. What about any investigation
11 with respect to Mallinckrodt or Endo or
12 any of the other companies that you are
13 aware manufacture opioids?

14 A. I'm not aware --

15 MR. WATTS: Objection to
16 form.

17 THE COURT REPORTER: Can I
18 ask who said that?

19 MS. CONROY: Who was that?

20 MR. WATTS: Ryan Watts.

21 BY MS. CONROY:

22 Q. Do you know if there has
23 ever been a Corporate Integrity Agreement
24 in place at Janssen or Johnson & Johnson?

1 A. Yes.

2 Q. And do you -- do you
3 understand why that Corporate Integrity
4 Agreement was in place?

5 A. Yes.

6 Q. And why is that?

7 A. There was a concern about
8 wrongdoing, I think about some of the
9 activities related potentially to
10 marketing.

11 Q. Marketing of what?

12 A. I don't know. I just know
13 that there was a CIA. I don't know all
14 the -- at this point, I don't remember.
15 I might have known at one time.

16 Q. Is that with respect to any
17 product at Janssen, or do you know?

18 A. I don't.

19 Q. Was there any -- how do you
20 know there was a CIA?

21 A. Because we were told there
22 was a Corporate Integrity Agreement. We
23 had additional training on what that'd
24 be.

1 Q. And you had additional
2 training with respect to marketing?

3 A. Actually I'd like to amend
4 something I said. I think the Corporate
5 Integrity Agreement may have been related
6 to Risperdal. I'm not certain about
7 that. Your question earlier about -- was
8 investigating about opioids, if I'm
9 correct. And I don't recall anything
10 with that.

11 Q. Okay. Was the CIA still in
12 effect, do you know, when you left
13 Janssen in 2017?

14 A. I'm not sure when the CIA
15 was completed. I know that I had taken
16 training, additional training for a
17 period of time.

18 Q. And the training concerned
19 proper marketing?

20 A. Proper marketing and a
21 number of different activities, yes. It
22 was extensive training, which was
23 mandatory at the company.

24 Q. Did you ever have anything

1 to do with Risperdal?

2 A. No. I don't think so. I
3 might have had -- well, at the company?
4 Is that what you're --

5 Q. Yes.

6 A. Right. I might have been
7 involved in some consulting activities
8 for Janssen with Risperdal when I was at
9 Parexel. But I interpreted your question
10 about whether I actually worked with
11 Risperdal as a Janssen employee. Is that
12 what you were looking for?

13 Q. I was.

14 A. And I did not work on the
15 drug when I was there.

16 Q. And what about when you were
17 on the promotional review committee.
18 Would you have had any occasion at that
19 time to review any of the marketing for
20 Risperdal?

21 A. No, I did not.

22 Q. Was your involvement in the
23 promotional review committee restricted
24 to pain products or opioid products?

1 A. I worked on opioid
2 analgesics, yes.

3 Q. Just opioid analgesics?

4 A. Correct.

5 Q. But if we take a look at
6 Page 344 of your CV. You were moving up.
7 You started in Titusville. And then you
8 moved to Raritan; is that correct?

9 A. Yes. It was another campus.

10 Q. Okay. And did your
11 responsibilities change from 2005 when
12 you left Titusville and then you were in
13 Raritan? Did your day-to-day
14 responsibilities change?

15 A. I worked on a different
16 opioid analgesic in Raritan. I may have
17 still had some activities related to the
18 compound that I was working on at that
19 point, which was Duragesic. But I also
20 acquired new responsibilities for
21 tramadol.

22 Q. When you were in Titusville,
23 did you work on Duragesic?

24 A. Yes.

1 Q. That was up through January
2 of 2005?

3 A. Yes. I may have had some
4 additional residual activities with
5 Duragesic as well. But more of my time
6 was spent with tramadol. Because of my
7 background and experience with Duragesic,
8 I certainly may have been on certain
9 documents and asked to render opinions
10 about Duragesic after 2005.

11 Q. When would you say -- I
12 realize this is approximate, we'll -- we
13 will look at documents. Where would you
14 say you basically were finished with any
15 work on Duragesic?

16 A. Around the time that the
17 drug went generic, approximately
18 around -- around 2005 or thereabouts.
19 The dates are approximate. So I want to
20 be clear on that.

21 Q. Okay. And then were you
22 working on tramadol prior to 2005? Or
23 let me ask this. Was there -- was there
24 some sort of a crossover with Duragesic

1 and tramadol?

2 A. There was a little bit of a
3 crossover, yes.

4 Q. Okay. What were your
5 responsibilities with respect to
6 Duragesic when you -- if -- kind of give
7 me an overview of -- starting in 2000 --
8 Duragesic was around in 2000, correct?

9 A. Yes.

10 Q. -- up until it went generic
11 in 2005. What -- give me an overview of
12 what involvement you had with that drug.

13 A. So I was a medical director
14 working on the compound. And then I
15 worked as a senior medical director as
16 well. So I was responsible for
17 postmarketing activities to support the
18 clinical development of a compound.

19 I had worked on analysis of
20 clinical studies, clinical trials. I
21 participated working with the regulatory
22 group on regulatory issues that may have
23 come up. I worked with our outcomes
24 research group. I was also involved in

1 working in one of my capacities at the
2 company, developing an acute surveillance
3 program for our opioid analgesics. And
4 Duragesic was the first compound involved
5 in those activities for me.

6 Q. And you had explained to me
7 earlier the types of postmarket work.
8 One of those would be company-sponsored
9 clinical trials?

10 A. Yes, that's correct.

11 Q. And you worked on those?

12 A. Yes. Those studies would
13 have been undergone -- those were
14 undertaken before I had gotten there. So
15 it was finishing up that work.

16 I may have had activities
17 with the investigator-initiated studies
18 as well. Remember we talked about
19 different types of postmarketing
20 activities, and I was involved, again,
21 working with our outcomes research group
22 developing information on
23 outcomes-related activities to support
24 the study.

1 I would provide medical
2 information -- medical expertise to our
3 medical information group. And I just
4 mentioned to you, I developed the acute
5 surveillance program for Duragesic.

6 Q. Were you involved in any --
7 strike that.

8 Outcomes research, was
9 that -- was that connected with
10 promotional activities for the drug?

11 A. No. The promotional
12 activities for the drug would have been
13 carried out through the promotional
14 review committee. The outcomes research
15 group was developing outcomes-related
16 data that might be used to provide
17 information to various groups. Payers
18 might be interested, for example, and
19 other groups as well. Provide also
20 information to clinicians that would be
21 of interest to them.

22 Q. But you would not consider
23 that promotion?

24 A. No. The outcomes -- the

1 data that were generated from the
2 outcomes research group would not
3 necessarily have comported with the FDA
4 requirement for the level of evidence
5 that was needed to be used for
6 promotional purposes. So that data was
7 supported and used in other types of --
8 for other -- other situations.

9 Q. The FDA has to approve any
10 studies that will actually be used for
11 the marketing of a product, correct?

12 A. I'm not sure I completely
13 understand your question.

14 Q. If data is going to be used
15 to market a product --

16 A. Yes.

17 Q. -- the FDA must approve that
18 data or they have to approve the data and
19 say that it's appropriate for promotion?

20 MR. LIFLAND: Object to the
21 form of the question.

22 THE WITNESS: The data that
23 would be used for promotional
24 materials would have to be from

1 well controlled studies, and
2 typically those are some of the
3 studies that would be used to
4 inform the product label.

5 BY MS. CONROY:

6 Q. And the same would be true
7 of any postmarket studies; it would have
8 to be well controlled studies?

9 A. If they were going to be
10 used for promotional purposes, yes.

11 Q. And the FDA would need to
12 approve them, correct?

13 A. Some of -- the information
14 would be sent down to FDA. FDA would
15 have an opportunity to review it and
16 opine on it. They may or may not
17 necessarily get back with a formal
18 approval. But it would have been
19 submitted for FDA review.

20 Q. You must submit it, correct,
21 if you're going to use it for promotional
22 material?

23 A. Promotional materials that
24 would have been used would have been

1 submitted to what was DD -- what was
2 called DDMAC. I forgot what their new
3 name would be. FDA may or may not have
4 gotten back to the company as they would
5 review it. And they had the option to
6 comment should they wanted to.

7 Q. I understand that. But
8 there would -- there's certainly a
9 requirement that Johnson & Johnson needs
10 to submit any materials to the FDA if
11 they're going to use it for promotional?

12 A. Janssen would have certainly
13 submitted --

14 MR. LIFLAND: Object to the
15 form of the question. Sorry. Go
16 ahead and answer. I probably
17 talked over. Did you get it?

18 THE COURT REPORTER: No.

19 MR. LIFLAND: Okay. Give
20 your answer again. Sorry.

21 THE WITNESS: Janssen would
22 have done those activities. Yes.

23 BY MS. CONROY:

24 Q. They would need to submit to

1 the FDA?

2 A. Yes.

3 Q. Now, for what reason would
4 outcome data be given to payers?

5 A. If there was a request for
6 that type of information.

7 Q. Where would the request come
8 from?

9 A. From the payers themselves,
10 there was information, for example, on
11 how the products might be used. There
12 may be information how it would be used
13 as part of usual care. That type of
14 information. Payers was one group. The
15 information could be provided to
16 prescribers as well and to a number of
17 different people who wanted to
18 understand -- have that type -- so that
19 would be some of the type of information
20 that would be used -- generated from the
21 outcomes research group.

22 Q. And the outcomes research
23 group would actually generate data,
24 correct?

1 A. They would generate data or
2 they may take data from clinical studies
3 where certain types of outcomes,
4 instruments, would be included in those
5 clinical trials. So the example, quality
6 of life-type measures, those type of
7 things, would be included as a number of
8 instruments as part of a clinical study
9 and the outcomes research group would
10 take that data and analyze it. So they
11 may generate the data from their own
12 studies or use data from clinical trials
13 that they could -- analyze and then use
14 as needed.

15 Q. Any of the data that would
16 be used from a clinical trial, would that
17 clinical trial have to have been
18 submitted to the FDA?

19 MR. LIFLAND: Object to the
20 form of the question.

21 Go ahead and -- if you can
22 answer it, or you can ask for
23 clarification. I just made an
24 objection for the record.

1 THE WITNESS: I would need a
2 clarification on the question.

3 MS. CONROY: Please don't
4 coach the witness.

5 BY MS. CONROY:

6 Q. If a data was used from a
7 clinical trial, would that data from the
8 clinical trial have to have been
9 submitted to the FDA?

10 A. To be used for promotional
11 purposes?

12 Q. To -- to be used for any
13 purpose at all.

14 A. Not necessarily.

15 Q. So it could be used as
16 outcomes data for example, a payer,
17 without having been submitted to the FDA?

18 A. Yes. If the data would have
19 come from a clinical trial and there was
20 a request from the payers or if there
21 were data they wanted to be discussed,
22 then they could do that.

23 Q. And the distinction would be
24 whether or not that data was being used

1 for promotion?

2 A. So peer-to-peer
3 communications would -- would be
4 discussed if it was being used for
5 promotional purposes. Again, those data
6 would need to be handled differently.

7 Q. Who would that discussion --
8 where would that discussion take place as
9 to whether or not it was being used for
10 promotion?

11 A. The decision on how it would
12 be used. If it was going to be
13 incorporated as part of the promotional
14 materials, then it would certainly need
15 to have a different level of evidence
16 that FDA requires. If it was being used
17 for peer-to-peer communications, it would
18 not necessarily be discussed with FDA.

19 The clinical trial data
20 though, keep in mind, would have been as
21 part of the -- the approval process would
22 have been discussed with FDA. So the
23 results of the clinical studies, those
24 data could be shared with people.

1 Q. What I was getting at with
2 respect to the clinical data, would all
3 of the data that was collected during a
4 clinical trial, for example quality of
5 life or other instrument data, would all
6 of that have been provided to the FDA?

7 A. Yes. All of that would be
8 submitted to FDA as part of the
9 submission process for approval of the
10 product. So it won't be -- it would be
11 efficacy data, safety data. Another
12 study would presumably be sent to them as
13 well, for FDA to review.

14 Q. So if there was any quality
15 of life, for example data, that would
16 have been sent at the same time as the
17 clinical and the safety?

18 A. That's my understanding.
19 That would be my understanding.

20 Q. And where does that
21 understanding come from?

22 A. Because we -- when you look
23 and see the information that would be
24 submitted, anything that related to the

1 compound and exposure to patients I think
2 would be submitted to the FDA.

3 Q. Do you know if it was?

4 A. The -- the new drug
5 applications are extensive. There's a
6 lot of information in there. I'm not
7 able to comment on everything that was
8 sent down.

9 But certainly all the safety
10 and efficacy information was shared with
11 FDA and the other information. So I
12 can't say for certain that I saw that
13 data sent down to FDA.

14 Q. So it's possible that, for
15 example quality of life data that would
16 be used for some outcomes research to be
17 provided to payers may not have been
18 provided to the FDA in the -- in the NDA?

19 A. So the --

20 MR. LIFLAND: Object to the
21 form of the question.

22 THE WITNESS: The quality of
23 life information, it would have
24 been part of the information that

1 would be administered to patients
2 and that information would have
3 gone down to FDA.

4 The subsequent analysis that
5 would be done by an outcomes
6 research group and shared with
7 payers, those types of analysis
8 would not necessarily be shared
9 with FDA -- would not have been
10 shared with FDA.

11 BY MS. CONROY:

12 Q. That's the analysis,
13 correct?

14 A. Yes.

15 Q. What I'm talking about is
16 all of the data that would ultimately be
17 analyzed for any purpose at Janssen, all
18 of that data would have been provided to
19 the FDA?

20 A. Yes, I believe so.

21 Q. What is a peer-to-peer --
22 what do you mean when you say
23 peer-to-peer?

24 A. Peer -- peer-to-peer

1 discussions would be where it would be
2 individuals such as physicians,
3 pharmacists, or Ph.D.s would share that
4 information with healthcare providers or
5 pharmacists or Ph.D.s. So it would be
6 non-promotional interaction.

7 Promotional interaction
8 might be with the sales force interacting
9 with healthcare providers. Peer-to-peer
10 would be individuals with advanced
11 scientific and/or medical training
12 interacting specifically with healthcare
13 providers.

14 Q. Someone such as yourself?

15 A. Yes.

16 Q. So if you're talking to a
17 physician about the attributes of a
18 Janssen product, that would not be
19 considered promotion?

20 A. That had evolved with time.
21 At one time it was considered
22 peer-to-peer. It's still peer-to-peer.
23 But because we -- I worked at the
24 company, later on, and I don't remember

1 the date when it changed, it would have
2 been handled as promotional materials.

3 Q. Do you -- can you do it by
4 drug? Do you know whether you would have
5 been able to have conversations,
6 peer-to-peer conversations concerning the
7 attributes of Duragesic without it being
8 considered a promotional conversation?

9 A. I think early on in my time
10 at Janssen, I think it would have been a
11 peer-to-peer and we would have had those
12 types of conversations.

13 Later on, as I already
14 indicated, it would be considered
15 promotional. I think by the time we got
16 to tapentadol, and I just simply don't
17 recall the date when it changed over. I
18 don't recall.

19 Q. I understand. I'm just
20 trying to determine whether you can do it
21 by drug. So you think by tapentadol,
22 there would not be any longer this
23 peer-to-peer --

24 A. Counsel, I think so, but I

1 don't have the date in my head where I
2 can say definitely at this point in time
3 it went over.

4 Q. Okay.

5 A. Yep.

6 Q. Who do you -- who do you put
7 in the category of payer?

8 A. Individuals who would pay,
9 you know, insurance companies,
10 individuals like that, would be paying
11 for these products for their -- the
12 people in their plans, et cetera.

13 Q. Managed care organizations?

14 A. Yes.

15 Q. Group purchasing
16 organizations --

17 A. Yes.

18 Q. -- would you approve that?
19 Hospital groups?

20 A. Yes.

21 These are groups that I
22 didn't personally interact with.
23 Although I did have several advisory
24 boards with payers. But this -- the

1 outcomes research group were responsible
2 for those activities. There may have
3 been other people at the company as well,
4 but that was some of their activities.

5 Q. So for some period of time,
6 the outcomes research group could have
7 conversations for example, with managed
8 care organizations and discuss the
9 attributes of Duragesic and it would not
10 be considered promotion?

11 A. I think that's true. I'm
12 not certain. I'd have to check on that.

13 Q. How would you check that?

14 A. Well, I -- actually, I don't
15 know how I would check it at this point
16 in time. But I think at one point in
17 time that might have been true. But the
18 people who would have been in the
19 outcomes research group at that time
20 might have been pharmacists, Ph.D.s as
21 well. So they were individuals with
22 advanced scientific and medical -- and/or
23 medical training.

24 Q. So as long as someone in

1 Janssen had an advanced scientific or
2 medical degree, they could have
3 discussions about the attributes of a
4 product with a payer?

5 A. If they were appropriately
6 trained on the product and were in a
7 position to do that. So it would not --
8 it would be someone who was not on the
9 sales force.

10 Q. So is that the distinction,
11 if someone is on the sales force and
12 talking about a product, that's
13 considered promotion?

14 A. Today, people at the
15 company, if I was working at the company
16 today, wanted to engage in those
17 discussions, it would be considered
18 promotional.

19 I thought the conversation
20 we had was prior to implementing those
21 rules, earlier on, it would have been
22 people with appropriate scientific and
23 medical training who were trained on the
24 product and could speak authoritatively.

1 And those are individuals would have been
2 able to have -- we already agreed I don't
3 have the date when the transition took
4 place.

5 Q. I understand that, not
6 knowing the date. But there is a date
7 when it turns -- when it becomes -- if
8 the company -- if anyone at the company
9 is saying it, it's considered promotion,
10 correct?

11 A. Yes.

12 Q. And that's what it is today?

13 A. Yes.

14 Q. At some point that changed
15 and you're not certain of that date?

16 A. Correct.

17 Q. Prior to that date, when it
18 changed, was the bright line whether the
19 sales -- someone from the sales force was
20 talking about the product versus a
21 scientific or medical person at the
22 company was talking about the product?

23 A. Yes, I believe so.

24 Q. Who would be able, at

1 Janssen, to tell me the date when that
2 changed?

3 A. I don't know.

4 Q. When it -- when it went from
5 sales -- you know, when it went from just
6 the sales force that couldn't do it to
7 the entire company?

8 A. I don't know.

9 Q. What department, do you
10 know?

11 A. Regulatory affairs
12 presumably.

13 Q. Do you recall a time when
14 you were informed or trained that any
15 statements by any -- by anyone at the
16 company would be considered promotional?

17 A. I don't remember, no.

18 Q. Do you recall how you
19 learned that?

20 A. I might have asked the
21 question and said that -- because I was
22 presented scientific material and I
23 wanted to have clarity on how -- how
24 those conversations could take place and

1 what venue that would be. And someone
2 had explained to me that it would be
3 considered promotional and had to be
4 treated as such.

5 Q. So at some point you
6 yourself took it upon yourself to ask
7 someone at Janssen if you could continue
8 to discuss peer-to-peer?

9 A. Yes.

10 Q. And then you were told you
11 could not?

12 A. I was told that I -- how it
13 would be treated as promotional, yes.

14 Q. So is it possible that for
15 some period of time you were doing that
16 and it was considered promotion while you
17 were doing it?

18 A. No. It would have either
19 come through the regulatory group or it
20 would have been because we were
21 disseminating scientific information, to
22 make sure that we had that ahead of time,
23 that I could safely do that. No, I don't
24 believe so.

1 Q. So as you sit here today,
2 you don't believe that you ever
3 inappropriately promoted a product?

4 A. Not knowingly.

5 Q. I see the term "Pri-Cara,"
6 P-R-I-C-A-R-A, unit of Ortho-McNeil
7 Pharmacies?

8 A. Yes.

9 Q. Was that -- was that a
10 company that was acquired?

11 A. Johnson & Johnson had a
12 number of different operating companies.
13 Pri-Cara was one of those operating
14 companies in the U.S.

15 Q. Did that make any difference
16 with respect to your base salary, your
17 bonus, your stock options, anything, the
18 fact that you were actually working in a
19 unit of Ortho-McNeil?

20 A. No, it did not.

21 Q. Let's look at the front page
22 please. You say, "Provide top level
23 strategic leadership to CNS franchise
24 vice president and company president for

1 all analgesic activities for Janssen CNS
2 franchise."

3 What does CNS stand for?

4 A. Central nervous system.

5 Q. The first bullet point,
6 develop the U.S. strategy for the
7 development and dissemination of
8 scientific data for a novel analgesic.

9 A. Yes.

10 Q. Was that -- what's the novel
11 analgesic you're referring --

12 A. Tapentadol.

13 Q. Tapentadol?

14 A. Nucynta.

15 Q. And that is an opioid pain
16 medication?

17 A. Correct.

18 Q. Is it immediate release,
19 modified release, extended release?

20 A. There are two formulations.
21 There's an immediate release and an
22 extended release.

23 Q. Did you work on both?

24 A. Yes.

1 Q. Which came first?

2 A. The immediate release.

3 Q. Next one is

4 responsibility -- I'm sorry --

5 "Responsible for the strategy to evaluate
6 the change in scheduling status."

7 A. Excuse me, Counsel. I hate
8 to interrupt you. You had asked the
9 question of the timing of when we were --
10 became that we were aware that these were
11 all treated as promotional, that the
12 employees -- there may have been training
13 materials that came out from the company.
14 And I don't remember the dates of those.
15 But because of my interaction with the
16 regulatory affairs group, I worked with
17 them closely on promotional review
18 committee, that I might have become aware
19 of it before the training actually came
20 out.

21 And so that would have given
22 me additional information. You asked
23 about when you would know and how did you
24 would take it upon yourself. I wanted to

1 give an explanation.

2 Q. Okay. So if I -- which
3 department at Janssen is responsible for
4 training materials for the employees?

5 A. I don't know -- there is a
6 group that does that. And I don't -- and
7 we can check. But I know I checked with
8 regulatory myself. I have a
9 recollection, I don't know if it's
10 correct, that there may have been -- that
11 that issue may have been addressed. So
12 I'm a little hazy on it. But I do
13 remember speaking to the regulatory
14 promotional person on the promotional
15 review committee and checking in about
16 that. So I wanted to make sure I
17 clarified that.

18 Q. Was it during the time that
19 you were on the promotional review
20 committee?

21 A. Yes, I was on the
22 promotional review committee for some
23 time, so yes.

24 Q. Okay. Would it have been

1 any training with respect to the
2 Corporate Integrity Agreement?

3 A. It might have been. I don't
4 know. I'm not sure.

5 Q. That's a possibility?

6 A. It's possible. But again,
7 I'm not certain.

8 Q. And just to be clear, it's
9 possible during -- it's a possibility
10 that during the Corporate Integrity
11 Agreement training, that you learned that
12 peer-to-peer conversations would be
13 considered promotional activities?

14 MR. LIFLAND: Object to the
15 form of the question.

16 THE WITNESS: I'm not sure
17 during what period of time where
18 that would have been.

19 BY MS. CONROY:

20 Q. I understand that. My
21 question was, it's possible that it was
22 during the corporate integrity training
23 that you learned that peer-to-peer is
24 considered promotional?

1 MR. LIFLAND: Object to the
2 form of the question.

3 THE WITNESS: I can't
4 speculate. I don't know. I just
5 know it was promotional. I don't
6 remember the nature of who or when
7 it came through.

8 BY MS. CONROY:

9 Q. My question is, was it -- is
10 it possible that you learned that during
11 the Corporate Integrity Agreement
12 training? Is that a possibility?

13 MR. LIFLAND: Object to the
14 form of the question.

15 THE WITNESS: I'm not sure.

16 BY MS. CONROY:

17 Q. What are you not sure?

18 A. I'm not sure when it took
19 place.

20 Q. I understand that. That's
21 why I'm asking you, is it possible that
22 it took place during the time that you
23 had Corporate Integrity Agreement
24 training? Is that a possibility?

1 MR. LIFLAND: Object to the
2 form of the question.

3 THE WITNESS: I guess it's
4 possible.

5 BY MS. CONROY:

6 Q. The second bullet point,
7 "Responsible for the strategy to evaluate
8 the change in scheduling status of an
9 opioid based upon the review and analysis
10 of complex data from a variety of
11 sources."

12 Do you see that?

13 A. Yes.

14 Q. And which opioid were you
15 looking to change the scheduling status?

16 A. There was discussion
17 possibly about changing the scheduling
18 status of tapentadol.

19 Q. And was it changed?

20 A. No, it was not.

21 Q. Third bullet point is,
22 "Implemented a first-time payer strategy
23 that opened the way for successful
24 partnering with payers and our medical

1 team in the design and development of
2 data analyses relevant to this key
3 stakeholder."

4 Do you see that?

5 A. Yes.

6 Q. Okay. I'm just going to
7 break that down a little bit.

8 What's -- what's a first
9 time-payer strategy, or is there
10 something -- are you talking about this
11 was the first time or is this something
12 known as a first-time payer?

13 A. No. This was a -- the
14 activities that went on with payers had,
15 as we had talked about, had been really a
16 lot of work by the outcomes research
17 group. There was a lot of important
18 medical information that we thought would
19 be appropriate for payers. And so we
20 discussed ways to try and understanding
21 the -- what requirements or requests
22 payers might have and to be able to
23 provide them with scientific data
24 accordingly.

1 So that's why it was the
2 first time that the medical group had
3 been involved to provide, as requested,
4 information to payers.

5 Q. What do you mean by "as
6 requested, information to payers"?

7 A. So if payers had reached out
8 to the company or had interacted with
9 individuals at the company who regularly
10 worked with that group, if there was a
11 request for scientific information, then
12 they would have come to the medical group
13 and said, "Can you give us a presentation
14 on the clinical trial data?" That type
15 of work.

16 Q. Payers are responsible for
17 formularies, correct?

18 A. The formulary committees, I
19 think, would have been different. These
20 would have been insurance companies,
21 managed care, and those types of
22 individuals.

23 Q. But managed care
24 organizations have formularies, correct?

1 A. They do. But these weren't
2 direct interaction with the formulary.
3 That was not what -- these were not
4 people with whom we interacted.

5 Q. Who were you interacting
6 with?

7 A. People from companies like
8 Aetna. You know, the medical -- the
9 medical directors at some of those
10 companies.

11 Q. And is it your testimony
12 that the medical directors would not
13 inform the formularies?

14 A. No.

15 Q. For those companies?

16 A. No, I'm not saying that at
17 all. You asked who we interacted with.
18 That's who we interacted with, medical
19 directors.

20 Q. And what -- what type of
21 individuals are we talking about?
22 Scientists? Ph.D.s?

23 A. Physicians.

24 Q. M.D.s?

1 A. Physicians.

2 Q. Pharmacists?

3 A. Could be, yes.

4 Q. And they would have
5 questions about the Janssen opioids?

6 A. The clinical trials data.
7 Yeah. That you'd want to have an
8 understanding of the study design, what
9 the studies show, et cetera.

10 Q. And these are the clinical
11 trials that were submitted to the FDA as
12 part of the new drug application?

13 A. Could have been. Could have
14 been other studies that were
15 postmarketing that were ongoing as well.

16 Q. And if you're -- they would
17 not -- some of this could have been
18 outcomes research that was done after the
19 drug was approved?

20 A. Yes. Some of it could have
21 been.

22 Q. And some of that outcomes
23 research may have been done either inside
24 the company or outside the company?

1 A. These were usually studies
2 that would have been conducted by the
3 company outcomes group.

4 Q. And those studies, those
5 outcomes, would be discussed with the
6 payers?

7 A. If there was a request for
8 that type of information, yes.

9 Q. And how does -- how would
10 that request come about?

11 A. Well, let's say the medical
12 director said, do you have any
13 information on how the product would be
14 used in real world setting, how -- you
15 know, how do people get the drug, how do
16 they take the drug, that type of
17 information. And then we would provide
18 that, again in a peer-to-peer
19 interaction.

20 Q. Do you know what would have
21 initiated that request?

22 A. It might have come through
23 the -- it might have come through the
24 people interacting. Counsel, I also

1 wanted to clarify one thing about
2 peer-to-peer versus promotional because I
3 want to make sure we do that correctly.

4 My understanding with that
5 would be -- on how we interacted with
6 them would be certainly if we were at
7 certain types of meetings later on, we
8 wanted to make sure that the material was
9 up to speed and consistent with our
10 promotional activities, where before that
11 there was a different requirement.

12 Q. Before that, what you mean
13 by that is it did not have to be
14 submitted to the FDA, correct, the
15 materials that would be provided in a
16 peer-to-peer meeting?

17 A. Right. So the posters for
18 example would not necessarily -- would
19 not have been presented to FDA, yes,
20 that's correct.

21 Q. They would not have been
22 presented to the FDA, but you -- at the
23 time we're talking about, you would have
24 been able to use the data from a poster

1 or the poster itself, you would have been
2 able to bring that to a meeting, discuss
3 it --

4 A. Yes.

5 Q. -- peer-to-peer?

6 A. Yes, exactly. And then
7 promote -- yes, that's correct, because
8 promotional activities would have been
9 done in a different place at the meeting.
10 Those were clearly defined as
11 promotional. After the change, then all
12 of these -- again, in our interaction
13 with people would be treated more in a
14 promotional way in terms of the label,
15 how we would interact with people.

16 Q. And you understood that to
17 be the company policy?

18 A. That was my understanding,
19 yeah.

20 Q. Do you know one way or the
21 other whether the rules at the FDA
22 changed?

23 A. I don't know.

24 Q. Sales -- and to be clear, a

1 sales representative could not talk about
2 results from a poster that was presented
3 unless that poster had been provided to
4 the FDA and -- well, provided to the FDA?

5 A. Unless that poster had been
6 approved by the promotional review
7 committee for discussion, yes.

8 I'd like to take a break.

9 Q. Let me -- before I do that,
10 I think -- I think I had a question on
11 the table. And then you wanted to
12 clarify something. I just didn't want to
13 forget it. So if you can give me two
14 seconds.

15 A. Sure.

16 Q. I had asked you, do you know
17 what would have -- you told me that the
18 medical director would ask if you had
19 information about the product in a
20 real -- real world setting? Do you
21 remember that --

22 A. That would be the -- that
23 would be an example of the type of
24 outcomes information there would be. The

1 other type of data -- so the data that we
2 would share would be clinical trial data.
3 They would want to know, for example, if
4 we had various types, not only efficacy
5 data, safety data would be very
6 important. They would want to have that.
7 If we had information on -- from outcomes
8 instruments that were included as part of
9 the clinical studies and they would share
10 that data with them as well.

11 Q. And then what I had asked
12 you is, do you know who might have
13 initiated that request?

14 A. So there were individuals at
15 the company that would have worked with
16 the managed care organizations. And if
17 the managed care organizations were
18 interested in having clinical data, then
19 they -- in having a discussion with
20 clinical people, or the outcomes group,
21 then they would have requested, and
22 that's how that would have taken place.

23 Q. And that's how they would
24 set up the meeting or whatever?

1 A. Typically, yes.

2 Q. And who -- what type of
3 individual at the company, what
4 department would they be in?

5 A. I think some of them may be
6 involved in marketing. But there may
7 have been other -- there may have been --
8 there may have been other -- the outcomes
9 research -- the outcomes group themselves
10 had individuals who also visited the
11 managed care organizations. And these
12 were people who would have been PharmDs,
13 pharmacists as well.

14 So it was interacting at a
15 professional level as well as, you know,
16 again, people with marketing experience.
17 So there were multiple places in which
18 they would have interacted.

19 Q. I see. So there -- there
20 was no prohibition from anyone at Janssen
21 going out and meeting with these managed
22 care organizations or insurance groups,
23 and then if someone at that meeting said
24 I'd like to know more about the safety of

1 this drug or the efficacy, then that --
2 you would consider that a request to get
3 involved and provide that information?

4 A. Right. So if there was --
5 if there was a -- right. So the
6 individuals who routinely interacted with
7 these groups, again as part of their
8 responsibilities at the company, if there
9 was a request by those groups to get
10 additional information, that could be
11 provided to them.

12 MS. CONROY: Okay. Let's
13 take a break. Thank you.

14 THE VIDEOGRAPHER: Remove
15 your microphones. The time is
16 12:06 p.m. We are going off the
17 record.

18 (Lunch break.)

19 THE VIDEOGRAPHER: We are
20 back on record. The time is
21 1:06 p.m.

22 BY MS. CONROY:

23 Q. Doctor, did you have any
24 conversations with Dr. Moskovitz after

1 his deposition?

2 A. No, I did not.

3 Q. Are you still in contact
4 with him at all?

5 A. No, I am not.

6 Q. Are you in contact with any
7 Johnson & Johnson or Janssen employees
8 after you left the company in 2017?

9 A. I have one person from the
10 department that I worked at, Steve
11 Rodriguez. He and I are friends
12 socially.

13 Q. Okay. Have you had any
14 conversations with anyone in the
15 department about anyone's deposition or
16 your -- what would have been your
17 upcoming deposition?

18 A. No, I did not.

19 Q. I saw on your resumé that
20 you are a member, if you look to Page
21 349, of the American Pain Society.

22 Do you see that?

23 A. Under memberships and
24 societies?

1 Q. Yes.

2 A. Yes.

3 Q. And are you still a member?

4 A. No, I'm not.

5 Q. Okay. When did you cease
6 being a member?

7 A. A number of years ago. I
8 had joined, and then just decided I
9 didn't want to pay the fees anymore for
10 it, so...

11 Q. So was that something that
12 you joined personally? It was not
13 something that was paid for by Janssen or
14 Johnson & Johnson?

15 A. I don't remember if they
16 paid for it or not. There were certain
17 things -- I assume that's -- yeah, I
18 don't remember.

19 Q. Okay. Do you recall that at
20 some point you made a decision not to be
21 a member anymore?

22 A. Just because I didn't want
23 to incur the expense. For no other
24 reason, yeah.

1 Q. Is there a publication or
2 anything that comes along with the
3 American Pain Society?

4 A. I believe there is a journal
5 that they're associated with.

6 Q. And so did you stop
7 subscribing to that as well when your
8 membership ended?

9 A. Yes.

10 Q. Did you -- was there any
11 reason to tell Janssen or Johnson &
12 Johnson that you were going to give up
13 your membership in the American Pain
14 Society?

15 A. No.

16 Q. But it was during the time
17 that you were employed at Janssen?

18 A. I believe so.

19 Q. The next is the American
20 Academy of Pain Medicine. Are you still
21 a member of that academy?

22 A. No. No, I'm not.

23 Q. And when did that cease?

24 A. I don't recall.

1 Q. Around the same time as the
2 American Pain Society?

3 A. Probably not that far
4 different in time. I decided that I
5 didn't necessarily need to maintain a
6 membership there as well. Again, for no
7 other reason than cost.

8 Q. American Academy of Pain
9 Management, are you a member?

10 A. No, I'm not.

11 Q. Same situation as the
12 others?

13 A. Yes.

14 Q. Did you ever attend any of
15 the conferences conducted by the American
16 Pain Society, the American Academy of
17 Pain Medicine or the American Academy of
18 Pain Management?

19 A. Yes. I attended some of the
20 annual meetings for these societies.

21 Q. And do you -- did you have
22 a -- did you attend them on any regular
23 basis?

24 A. I tried to go annually if I

1 was able to do so.

2 Q. Which ones would you try to
3 go to annually?

4 A. The American Pain Society
5 was an important one. And I don't
6 remember now if it was the American
7 Academy of Pain Medicine or the American
8 Academy of Pain Management. But I went
9 to meetings with both, as I had
10 indicated. But I don't -- it was at one
11 of those, and I don't remember which one
12 I had gone to more frequently.

13 Q. I could barely hear you.
14 One of those, either the American Academy
15 of Pain Medicine or the American Academy
16 of Pain Management, one of those you went
17 to meetings more frequently --

18 A. Yes.

19 Q. -- than the other?

20 A. Yes, that's correct, yes.

21 Q. And where would those
22 meetings have been held?

23 A. Throughout the United
24 States.

1 Q. And approximately -- was
2 there, if you know, a difference in the
3 size of those meetings that were held
4 around the United States, among the
5 three, American Pain Society, American
6 Academy of Pain Medicine, and American
7 Academy of Pain Management?

8 A. To the best of my
9 recollection, I think the American Pain
10 Society had a fairly large number of
11 people attending. And the other
12 societies, had, I believe, fewer people
13 and with time that may have changed.
14 There may have been more people going.

15 Q. Okay. And do you recall
16 approximately how much it was to join any
17 of them?

18 A. I don't.

19 Q. Do you know if it was in the
20 hundreds of dollars or the thousands of
21 dollars?

22 A. It would have either been
23 hundreds of dollars or maybe a thousand.
24 Somewhere around there.

1 Q. Would that be a year?

2 A. Yes.

3 Q. And were there criteria to
4 join?

5 A. I don't recall. I don't
6 recall if you had to have some kind of a
7 background in medicine. I don't
8 remember.

9 Q. And was there -- were there
10 any tiers of membership in any of the
11 three, you know, for example that, you
12 know, a layperson could join and have
13 access to certain events or subscriptions
14 or publications, and then a medical
15 doctor would potentially have more
16 access, anything like that?

17 A. Not that I recall.

18 Q. Did you ever sit on any
19 committees for any of those -- any of
20 those three?

21 A. I did not. Not that I
22 recall.

23 Q. What was the American
24 Society of Addiction Medicine?

1 A. This was something that I
2 had joined. I was interested in this
3 area. I may have had a subscription for
4 a year or so. I don't remember how long
5 I stayed with them. It was a society
6 that I became more -- I learned about
7 them later on and it was something that I
8 had wanted to join. And I joined for a
9 period of time. I'm not a member of the
10 society anymore.

11 Q. Okay. Approximately when
12 did you become interested in addiction
13 medicine to warrant joining this?

14 A. Well, for a long time I
15 didn't realize that this society existed.

16 Q. What is the nature of the
17 society? Who are the members, or at
18 least who are the members when you were a
19 member?

20 A. I think there were people
21 who either treated people with addiction
22 or had an interest in addiction.

23 Q. Do you know if Johnson &
24 Johnson paid for your membership?

1 A. I don't recall.

2 Q. Do you know if there were
3 corporate memberships of American Society
4 of Addiction Medicine?

5 A. I don't know.

6 Q. And did they have any kind
7 of annual or biannual meetings?

8 A. I don't know for a fact that
9 they did. I suspect that they did. But
10 I don't know.

11 Q. Okay. Do you recall ever
12 attending one?

13 A. I did not.

14 Q. You did not attend?

15 A. I did not attend, no.

16 Q. What did you get for your
17 membership?

18 A. It would have been
19 information about upcoming meetings,
20 things that were going on in the society
21 that I thought might have been
22 potentially of interest to me.

23 Q. And was there anything of
24 interest?

1 A. I was interested in what
2 they were doing. But I did not join any
3 of those -- any of those meetings or any
4 of those activities.

5 Q. And did you learn what they
6 were doing?

7 A. I read about some of the
8 things that would come in to me by e-mail
9 or other ways that they would have
10 contacted me.

11 Q. Do you recall what any of
12 those were, things that they were doing?

13 A. I don't offhand, not
14 specifically, events.

15 Q. I know that you -- you have
16 a list of publications and poster
17 presentations. If we take a look on Page
18 8 of your CV, you have a tapentadol IR
19 versus oxycodone IR. I guess this is --
20 maybe you tell me, a publication that was
21 presented at the Fifth World Congress of
22 the WIP in New York?

23 A. What page are you on?

24 Q. I'm on Page 8 which is also

1 530. The very top one.

2 Fifth World Congress of the
3 WIP, New York 2009 in March. Do you see
4 that?

5 A. I do.

6 Q. What's the WIP?

7 A. I don't recall. It's
8 "world" and "pain." But I don't remember
9 what the I stands for.

10 Q. Okay. Something like
11 institute or something like that?

12 A. It could have been, but I
13 don't want to guess.

14 Q. Okay. And was this a
15 publication or was it a poster?

16 A. It was -- to the best of my
17 recollection it was a poster
18 presentation.

19 Q. And this would have been
20 done -- the et al. means it was done with
21 some other co-authors?

22 A. Yes.

23 Q. And would this poster have
24 been done while -- as a part of your

1 employment at Johnson & Johnson?

2 A. I'm not sure what -- I don't
3 understand the question.

4 Q. This study, tapentadol IR
5 versus Oxycodone IR for low back or
6 osteoarthritis pain, dose escalation and
7 pain control, I take it there was some
8 sort of a study that was done to compare
9 those two drugs?

10 A. That's correct.

11 Q. And were -- was there a
12 clinical study done?

13 A. Yes.

14 Q. And was that clinical study
15 a Johnson & Johnson-sponsored study?

16 A. Yes.

17 Q. And it was not an
18 investigator -- it wasn't a postmarket
19 investigator study?

20 A. Correct.

21 Q. And so would you have been
22 involved at Johnson & Johnson with
23 respect to that clinical study?

24 A. I'm not sure what you mean

1 by involved.

2 Q. Well, since you are an
3 author on it, on the poster, correct?

4 A. Yes.

5 Q. What involvement did you
6 have in order to become an author on the
7 poster?

8 A. I analyzed the data and put
9 it together and helped write the poster.

10 Q. Do you have a memory of who
11 collected the data for this poster?

12 A. I don't.

13 Q. Would there be records
14 somewhere that would show the clinicians
15 involved in collecting the low back or
16 osteoarthritis pain data with respect to
17 those two drugs?

18 A. Yes. This would have
19 been -- yes, it would have been possibly
20 done, if it's studied through the R&D
21 group. They would have had the
22 information of the people working,
23 working on it.

24 Q. And I think you told me

1 earlier today that you no longer have any
2 copies of any of the posters --

3 A. That's correct.

4 Q. -- that you presented?

5 Is there a reason for that?

6 A. I had retired from the
7 company and I wasn't working directly
8 with the company anymore. And I didn't
9 see the need to keep any of this
10 documentation. It was published. It was
11 in the public domain. I can refer back
12 to it at any point in time if there was
13 interest in it. So I didn't need to
14 retain a personal copy for myself
15 anymore.

16 Q. And if you did want to get a
17 copy of it, how would you -- how would
18 you do that?

19 A. I could go online and see if
20 it was available. And then if I -- or I
21 could write -- just like anyone else,
22 write to the company and see if I could
23 get a copy of it as well.

24 Q. So you could -- you could

1 either write to Johnson & Johnson and ask
2 for a copy, or it may be available from
3 the fifth World Congress of the WIP?

4 A. It might be.

5 Q. I'm sorry?

6 A. It might be, yes.

7 Q. Have you ever tried to get a
8 copy of the poster?

9 A. No, I have not.

10 Q. Would there have been any
11 sort of a publication or abstract
12 presented along with the poster or
13 submitted along with the poster?

14 A. Yes. There would have been
15 the poster itself and/or an abstract.
16 And it's -- different societies work
17 differently. Would have published it in
18 a -- in a volume.

19 Q. And so you would anticipate
20 that there is a published version of this
21 poster in any company abstract somewhere?

22 A. One -- one was done. I
23 don't know from record retention in 2009
24 whether it would still be. But, yes.

1 With something like that -- different
2 societies work differently in terms of
3 how those were -- those were handled.

4 Q. And when that poster was
5 presented, would you have -- would you
6 have been present and -- they -- they
7 blow these posters up very large,
8 correct, at -- at the conferences?

9 A. Yes.

10 Q. And would you have been
11 standing with the poster?

12 A. I might have.

13 Q. And if you -- if you were
14 there, would you have been there to
15 answer any questions about it?

16 A. Yes.

17 Q. Do you recall whether or not
18 you gave a presentation to the group
19 about the results of that poster that was
20 different from standing by the poster and
21 answering any questions?

22 A. Could you clarify what you
23 mean by the group?

24 Q. The -- was the World

1 Congress of the WIP, I assume that's a --
2 also a membership group that gets
3 together?

4 A. You mean people who attended
5 the meeting? You mean like a podium
6 presentation or something?

7 Q. Well, I -- maybe I should
8 ask you first. What is the fifth World
9 Congress of the WIP? Is that a -- is
10 that a group of individuals that get
11 together or that did get together in New
12 York in 2000 -- 2009?

13 A. Yes.

14 Q. And so would there have been
15 a podium and a -- in some sort of an
16 auditorium?

17 A. This -- this, I believe, was
18 just a poster presentation, yeah.

19 Q. So individuals who attended
20 this congress could walk through a hall
21 and take a look at any of the posters
22 that were being presented?

23 A. Correct.

24 Q. Is that true -- I -- because

1 I see the next one down is another poster
2 comparing tapentadol concerning nausea
3 and vomiting.

4 Do you see that?

5 A. Yes.

6 Q. The next -- the next one
7 down? Same thing, that was a poster that
8 was presented in the hall?

9 A. Yes.

10 Q. And the same thing for the
11 third one. This one was analysis of
12 treatment discontinuation. Do you see
13 that?

14 A. Yes.

15 Q. And that, same thing,
16 actually the top four, all of those were
17 presented in March of 2009 in New York?

18 A. Yes.

19 Q. And all four were posters?

20 A. That is correct.

21 Q. Take a look at the bottom of
22 the page. There's several authors, you
23 are one of them. Dose conversion for
24 immediate to extended-release tramadol.

1 Do you see that?

2 A. Yes.

3 Q. Presented at the American
4 Academy of Pain Management.

5 That would have been one of
6 the yearly meetings; is that correct?

7 A. I didn't -- I didn't hear
8 you.

9 Q. Would that be one of the
10 yearly meetings, the American Academy of
11 Pain Management?

12 A. Yes.

13 Q. And you would have -- and
14 that looks like that year in
15 September 2006 it was in Orlando,
16 Florida, correct?

17 A. Yes, yes.

18 Q. And would this have been a
19 poster, or -- do you recall, or was it an
20 abstract?

21 A. I don't recall.

22 Q. Do you recall if you made
23 any sort of a presentation to a group
24 from a podium?

1 A. For this particular?

2 Q. For that particular one.

3 A. I -- no, I do not recall
4 that.

5 Q. Would this be considered
6 peer-to-peer?

7 A. Yes.

8 Q. So would there be any reason
9 that you know in 2006 to present this
10 dose conversion for immediate to
11 extended-release tramadol data to the
12 FDA?

13 A. This was based on a clinical
14 trial that was done by Janssen so those
15 data likely would have been presented to
16 FDA.

17 Q. Okay. Were you involved in
18 that clinical trial or only in the
19 presentation?

20 A. I was not involved in the
21 clinical trial. Only involved in
22 analyzing the data for the presentation.

23 Q. Take a look at the next
24 page, 351. I see the name Katz, NP Katz.

1 Is that Dr. Nat Katz?

2 A. Yes, it is.

3 Q. And was he someone that you
4 worked with while at Johnson & Johnson --
5 but he was not of Johnson & Johnson,
6 correct?

7 A. He was not at Johnson &
8 Johnson. And yes, I did work with him
9 when I was at Johnson & Johnson.

10 Q. All right. Are you still in
11 contact with him?

12 A. No, I'm not at the moment.

13 Q. And when is the last time
14 you spoke to him?

15 A. I think I communicated with
16 him to tell him that I was retiring from
17 J&J. From Janssen.

18 Q. Do you know if he still
19 works with J&J?

20 A. I don't know.

21 Q. Was he still working with
22 J&J when you retired?

23 A. I don't know.

24 Q. When is the last time you

1 worked on a project with Dr. Katz?

2 A. I don't recall.

3 Q. Do you recall what the last
4 project was with Dr. Katz?

5 A. No, I do not.

6 Q. Certainly you would have
7 worked with him, from looking at this, in
8 2004, correct?

9 A. Yes.

10 Q. Did you work with Dr. Katz
11 with respect to tapentadol, do you
12 recall?

13 A. I recall having some
14 conversations with him about tapentadol.

15 Q. And that would also be with
16 respect to Nucynta?

17 A. Yes. So tapentadol and
18 Nucynta are -- are the same drug.

19 Q. And did you -- do you recall
20 if Dr. Katz did any work on any clinical
21 studies for Nucynta or tapentadol?

22 A. I don't recall.

23 Q. Did you -- did he do
24 clinical study work, Dr. Katz?

1 A. Yes, he did.

2 Q. Was he a site, clinical
3 study site?

4 A. I believe that he was
5 associated with a site. I don't know if
6 it was his site or not.

7 Q. Is he in Boston?

8 A. That's correct. But he's
9 actually, I think, in Newton.

10 Q. Newton?

11 A. Yes.

12 Q. If you take a look at the
13 first page again. And we were talking
14 about payers before the lunch break, and
15 I think you told me that a payer could be
16 an insurance company, managed care
17 organization, hospital group.

18 Do you know if CVS is a
19 payer?

20 A. I'm not sure I understand
21 your question.

22 Q. Okay. Do you know, you
23 listed out for me entities that you
24 understood from your employment at J&J

1 that were considered payers?

2 A. Yes.

3 Q. Do you recall that
4 testimony?

5 A. I do.

6 Q. And you had listed out, you
7 told me, Aetna, some insurance companies,
8 some managed care organizations. I asked
9 you about hospitals or hospital groups.
10 And you agreed that they could be payers?

11 A. Yes.

12 Q. Do you have -- do you have
13 any recollection if any chain pharmacies
14 were payers?

15 A. That we worked with? Is
16 that -- or just in general?

17 Q. Well, either one?

18 A. I don't remember who we
19 worked with, per se. It certainly could
20 be people who could be considered payers.
21 But I don't recall if we worked with them
22 or not, if I worked with them. That's
23 what I'm talking about.

24 Q. Do you recall if Johnson &

1 Johnson worked with any chain pharmacies?

2 A. I don't know.

3 Q. Do you know -- would you
4 consider a chain pharmacy to be in the
5 supply chain?

6 A. I'm not sure what you mean
7 by that.

8 Q. We're going to look at some
9 documents, some PowerPoints of yours that
10 reference supply chain, and supply chain
11 oversight and supervision. And so I'm
12 talking about it in that context.

13 A. Would they be part of the
14 supply chain? Is that your question?

15 Q. That's my question.

16 A. Yes, I believe that they
17 would be.

18 Q. But you don't have any
19 recollection yourself of working with any
20 particular chain pharmacy?

21 A. Not myself, that I recall.

22 Q. There would be no reason, if
23 there was information requested of you,
24 such as you were discussing with me that

1 insurance company might have some
2 information about clinical trials or drug
3 attributes, there would be no reason if
4 CVS asked that question, that you
5 wouldn't provide that information to
6 them; is that true?

7 A. It may not be -- it may not
8 have been me. It might have been someone
9 else at the company. But if there was a
10 request for scientific information, then
11 it would have been provided by the
12 appropriate people.

13 Q. The next bullet point that
14 says, "Design the strategy with key
15 stakeholders to better understand the
16 data need of groups who develop quality
17 measures for analgesics to ensure that
18 data generated on our products inform
19 quality measures. Do you see that bullet
20 point?

21 A. I do.

22 Q. Who is a key stakeholder?

23 A. So this might have been, for
24 example, people who are working in

1 clinical practices and those types of
2 individuals as well. And working
3 specifically with groups that might be
4 interested in developing quality measures
5 to understand the type of data needs that
6 they have.

7 So there were different
8 organizations that the company partnered
9 with. I worked with those groups within
10 the organization to understand what they
11 might be. The area of quality measures
12 for analgesia was one that was actually
13 in its infancy, it was early on. There
14 were quality measures with -- and
15 replaced with other things, so we were
16 interested in understanding the needs
17 were of what those were particular
18 people.

19 Q. Can you give me some
20 examples of quality measures for
21 analgesics?

22 A. Yes. Ensuring, for example,
23 measures of pain for patients with --
24 people with pain were done.

1 Understanding other types of measurements
2 that might be important to them as well,
3 what their level of functionality would
4 be, and what are the other types of
5 things that would show beneficial and
6 improvements with the product.

7 Q. What about product risks
8 such as addiction or withdrawal syndrome?
9 Would they ever be considered quality
10 measures?

11 A. They would need -- the
12 quality measures would really be the sum
13 of all of the effects of people might
14 have on it. So certainly understanding
15 and asking those questions of patients,
16 soliciting that type of information, to
17 ensure that patient care was done in its
18 totality. So not only were the
19 medications being given, but they were
20 looking for reduction in pain and for
21 side effects as well.

22 Q. And those side effects could
23 include addiction?

24 A. Yes, they could.

1 Q. And abuse or misuse?

2 A. That would be part of care
3 for a patient receiving any of these
4 types of pain medications, or should be.

5 Q. Did you generate data on
6 your products with respect to pain
7 measurements?

8 A. I'm not sure what you're
9 asking me.

10 Q. I see that you designed a
11 strategy with the key stakeholders. The
12 key stakeholders are clinicians and
13 others who are using the product,
14 correct?

15 A. Yes. And also, as I
16 indicated, people who were involved in
17 developing these types of measures.

18 Q. And could they also be
19 payers?

20 A. These were not payers, per
21 se. Yeah.

22 Q. To better understand the
23 data needs of groups who develop quality
24 measures --

1 A. Yes.

2 Q. -- for analgesics.

3 A. Yes.

4 Q. So did you ever develop
5 quality measures with respect to pain?

6 A. No. At this juncture we
7 were trying to understand the types of
8 measures that were potentially -- that
9 were available and the types of measures
10 that these groups would be interested in.

11 Again, these were groups
12 that were working with patient groups, et
13 cetera to understand the quality
14 measures. But we did not develop
15 specific measures.

16 Q. Okay. And that's true as
17 well, you did not develop any specific
18 quality measures concerning addiction?

19 A. That's correct.

20 Q. And you did not develop any
21 specific quality measures concerning
22 abuse or misuse?

23 A. Yes.

24 Q. Yes, you did not?

1 A. We did not. Yes, we did
2 not.

3 Q. Did you ever develop a
4 strategy to determine those quality
5 measures?

6 A. No. The intent was to work
7 with people who were actually doing --
8 developing quality measures,
9 understanding what their needs might be
10 and see if it -- early on, what are the
11 types of information that they may want
12 from us, but we did not do that
13 ourselves.

14 Q. Okay. Do you know if anyone
15 did it?

16 A. I don't know.

17 Q. Do you know to this day if
18 anyone did that?

19 A. I don't know.

20 Q. Are you aware of any studies
21 or measurements of addiction in patients?
22 With -- and I'm talking about with
23 respect to opioid products used for
24 chronic pain.

1 A. Oh, there were -- there are
2 published studies on the signs and
3 symptoms of addiction, but I'm not -- or
4 things to be looking for. But I'm not
5 aware of any specific studies.

6 Q. That measured addiction?

7 A. I'm not aware of studies
8 that measured addiction, per se.
9 Clinical trials, in some of them, would
10 sometimes include information, to answer
11 your question, on pill count to see
12 whether the medication, such as the
13 opioid pain medications, were
14 appropriately accounted for. But that
15 would have been part of the clinical
16 trial itself.

17 Q. You're not aware of any
18 actual measurements that were taken with
19 respect to, for example, rates of
20 addiction in patients taking chronic --
21 taking opioids for chronic pain?

22 A. From a clinical trial?

23 Q. From anything.

24 A. No, I'm not aware.

1 Q. And that's true through
2 today? Well, is it true through 2017?

3 A. I'm not aware of studies
4 that specifically looked at addiction as
5 a specific endpoint either on a
6 controlled clinical trial or in other
7 types of studies.

8 Q. Okay. Do you keep up with
9 the literature?

10 A. I have. But not as much
11 since I've been retired. So the
12 information post-retirement is a little
13 bit different than what it had been
14 before.

15 Q. Have you always kept up --
16 are you licensed to practice medicine in
17 Massachusetts?

18 A. Yes.

19 Q. And in New Jersey -- you
20 live in Pennsylvania?

21 A. Yes.

22 Q. What states are you licensed
23 in?

24 A. In Massachusetts.

1 Q. Okay. Just Massachusetts?

2 A. Yes.

3 Q. And you've kept that up?

4 A. Yes. I take the CME, et
5 cetera, to keep it up. Yes.

6 Q. And I didn't ask you, but
7 are you still a member of the Medical
8 Association of Massachusetts?

9 A. Yes.

10 Q. Any other associations that
11 you're currently a member of?

12 A. No.

13 Q. The fifth bullet point is
14 overall responsibility -- "Overall
15 responsible for medical lifecycle
16 planning for in-line analgesic
17 formations."

18 What does that mean?

19 A. So the -- for a product,
20 for -- as products are developed, they go
21 through a lifecycle. And what are the
22 possible ways that we might be able to
23 think about new indications or new ways
24 that they can be studied.

1 So I was responsible for
2 looking at that and seeing where there
3 are new and different ways that we might
4 be able to think about studies to provide
5 information to healthcare providers and
6 others about the use of the products.

7 Q. And was that through -- true
8 through 2017, when you left the company?

9 A. I left the company in 2017,
10 but the work I did in analgesia ended
11 when the U.S. rights for Nucynta were
12 sold to another company. I then worked
13 in infectious diseases for a period of
14 time. And then after that, I went back
15 to doing some projects. So I haven't
16 been specifically working in analgesia
17 since about 2015.

18 Q. Okay. Did your title change
19 at all in -- when you left analgesia and
20 went to infectious disease and special
21 products?

22 A. So I was doing -- my title
23 was senior director for clinical
24 development and infectious disease. And

1 I did that for approximately a year and a
2 half. And then between January and June
3 of 2017, I did some specific projects in
4 our central nervous system group. But
5 they were not analgesia related.

6 Q. And that basically updates
7 this, so from August 2013 to, if we
8 would -- this would be sometime in 2015
9 that you ended your analgesia work?

10 A. That's correct.

11 Q. Okay. And then from 2015 to
12 January of 2016, you worked on infectious
13 diseases?

14 A. Yes. Through the end of
15 2016, and then the -- the first six
16 months between January and June or
17 thereabouts.

18 Q. Oh, I see.

19 A. I went back to work in the
20 central nervous system, medical -- U.S.
21 medical affairs group and worked on some
22 other projects before I retired.

23 Q. And none of those involved
24 analgesics?

1 A. Correct.

2 Q. Did any of them involve
3 addiction or abuse?

4 A. Not while I was with the
5 company.

6 Q. And has anything occurred
7 after you left the company with respect
8 to looking into addiction or abuse?

9 A. Not -- no. Nothing --
10 not -- nothing at the moment.

11 Q. Do you have something in the
12 works?

13 A. Maybe.

14 Q. Okay. Are you -- I know you
15 said that you were not being paid for
16 your time. Is your -- is your company
17 being paid?

18 A. No.

19 Q. Were you familiar with the
20 label that was prepared in 2001 when you
21 began -- around the time that you were
22 working under Duragesic, would that have
23 been something you were familiar with,
24 the FDA label?

1 A. I would have to look at the
2 data to see -- I would have to look at
3 the label to see.

4 Q. What would you need to look
5 at the label --

6 A. To familiarize myself. I
7 haven't seen the label in a long time.

8 Q. I'm not asking a question
9 about the label. I'm just asking, as
10 part of your job responsibilities, would
11 the label have been something you were
12 familiar with?

13 A. Oh, I understand now. I
14 might have been asked to review a label
15 as -- as one of the people who worked in
16 U.S. medical affairs.

17 Q. And I know in your files I
18 saw some review, some later review of
19 labels, some back and forth with respect
20 to the FDA.

21 A. Yes.

22 Q. Is there a time that you
23 would have been more involved in labeling
24 with respect to Duragesic?

1 A. While I was working on the
2 compound prior to it becoming a generic,
3 I would have been involved in the label
4 conversations as these came along.

5 Q. And when did the product
6 become generic?

7 A. I think -- and the dates are
8 approximate. Some time in the -- some
9 time in the 2005 time range.

10 Q. And so at least as of 2005
11 you would have reviewed the label for
12 Duragesic?

13 A. I -- I would have been one
14 of the label reviewers, yes.

15 Q. And then when you became
16 involved with tapentadol and Nucynta,
17 would you have reviewed that label?

18 A. Yes.

19 Q. Would you have been -- would
20 you have been involved in the initial
21 drafting of that label for the approval
22 process?

23 A. I don't know that I was.
24 No, I'm not -- I'm not sure that I was.

1 Q. Is it fair to say that early
2 on in -- in the process, you would have
3 seen a label or a draft label for
4 Nucynta?

5 A. When it was being submitted
6 to the FDA for approval?

7 Q. Or anything. I'm just
8 trying to get an understanding. In your
9 role with Nucynta, is it something that
10 you would have seen the label --

11 A. Yes, at some point.

12 Q. -- typically?

13 A. But -- yes. But, yes,
14 certainly postapproval.

15 Q. Okay. Copies coming, but I
16 think I have enough of the 2001 label.
17 So -- but not many copies.

18 (Document marked for
19 identification as Exhibit
20 Janssen-Vorsanger-3.)

21 BY MS. CONROY:

22 Q. I'm going to mark as
23 Exhibit 3 -- and I have a -- just to help
24 you. What I've put up a Post-It note on

1 one page I'm going to ask you about, but
2 you are free to look at the whole label.
3 But just make it easier to find what I'm
4 talking about.

5 And this Exhibit 3 is the
6 2001 approval package, approved label for
7 Duragesic. The Bates number is
8 JAN-MS-02629790 through 824.

9 Does this look at all
10 familiar to you?

11 A. Yes, it does. Some time to
12 review it.

13 Q. And I understand you may not
14 have seen it in exactly this form. But
15 if the FDA approved this label format,
16 these words couldn't change, correct?

17 A. Once we received the
18 approved label from FDA, yes, that would
19 be the label.

20 Q. Okay. So if I look on
21 Page 1 of the label, which is Bates
22 Number 797, there's -- says "Duragesic,
23 fentanyl transdermal system," and then
24 the controlled substance symbol.

1 Do you see that?

2 A. Are -- are you on Page 1?

3 Q. I'm on Page 1 of -- it's
4 797.

5 A. I don't see 797. I just see
6 Page 1.

7 Q. Turn -- oh, I'm sorry.

8 MR. LIFLAND: Bates numbers.

9 MS. CONROY: I have a
10 different version.

11 BY MS. CONROY:

12 Q. Yeah. Do you see the one
13 with the -- oh, it looks like the same
14 thing. Yes. The black box, correct.

15 That's Page 1. And it says,
16 "Full prescribing information"?

17 A. Yes.

18 MR. LIFLAND: If you want to
19 double-check that we're reading
20 off the same document?

21 MS. CONROY: Yeah, I'm
22 right -- the Bates number is cut
23 off. I'm on Page 1.

24 MR. LIFLAND: Okay.

1 MS. CONROY: Okay. But it
2 is the same -- this is the same
3 document. It just has that
4 problem, if you don't --

5 MR. LIFLAND: Okay. Well,
6 maybe we --

7 MS. CONROY: We -- you know,
8 we printed it at the hotel. And
9 if they don't do the right -- if
10 they don't have the right margins,
11 you can't get the Bates number.

12 MR. LIFLAND: Why don't you
13 just read the Bates range into the
14 record and then we'll refer just
15 to the pages for --

16 MS. CONROY: Sure.

17 MR. LIFLAND: -- the native
18 page numbers in the document and
19 be able find our way through it.

20 MS. CONROY: It's -- it's
21 JAN-MS-02629790 through 824, but
22 there are also page numbers on the
23 document.

24 BY MS. CONROY:

1 Q. So what we're looking at
2 right now is Page 1, which is the full --
3 and it says, "Full prescribing
4 information for Duragesic."

5 Do you see that?

6 A. Yes, I see it. I'm looking
7 at Page 1.

8 Q. Okay. And this is a label
9 that would need to accompany every
10 Duragesic prescription until such time as
11 the FDA changed the label, correct?

12 A. Yes.

13 Q. And now if you would take a
14 look at Page 12. And that's where I put
15 the Post-It note.

16 And this is the drug abuse
17 and dependence section. Do you see that?

18 A. I do. Can I move the
19 Post-It up a little bit so I can read --

20 Q. Oh, you can take it off
21 entirely. I just used it to get you to
22 the right page.

23 I take it you have seen this
24 before today?

1 A. Yes.

2 Q. Okay. So if you take a
3 look, the first sentence says, "Fentanyl
4 is a Schedule II controlled substance and
5 can produce drug dependence similar to
6 that produced by morphine."

7 Do you see that?

8 A. Yes.

9 Q. Do you agree with that?

10 A. I do.

11 Q. "Duragesic fentanyl
12 transdermal system."

13 That means it's a patch,
14 right?

15 A. Yes.

16 Q. The transdermal system?

17 "Therefore, it has the
18 potential for abuse." Do you agree with
19 that?

20 A. Yes.

21 Q. "Tolerance, physical and
22 psychological dependence may develop upon
23 repeated administration of opioids."

24 Do you agree with that?

1 A. Yes.

2 Q. "Iatrogenic addiction
3 following opioid administration is
4 relatively rare."

5 Do you agree with that?

6 A. I do.

7 Q. And what is your support for
8 that statement?

9 A. Well, this is a statement
10 that had been in the package insert. So
11 it would have been supported at that
12 time. There were subsequent studies; I
13 believe that there was a Cochrane study
14 that was published. There's an article
15 by Michael Fishbain and coworkers looking
16 at iatrogenic addiction as well. And in
17 both of those taken together, it looks
18 like the rates of iatrogenic addiction
19 are -- were very low, are low.

20 Q. All right. Let me just
21 break that down a little bit.

22 So you understand that
23 this -- well, what do you understand
24 iatrogenic addiction to be?

1 A. Iatrogenic addiction is
2 addiction that occurs as a consequence of
3 receiving a medication prescribed by a
4 health -- healthcare provider.

5 Q. And you mentioned a
6 Dr. Fishbain?

7 A. Dr. Fishbain. An article
8 with Dr. Fishbain and co-workers looking
9 at iatrogenic addiction.

10 And there was also a
11 Cochrane review that was done. I believe
12 Dr. Chou was the senior author on that
13 Cochrane review. And both of those taken
14 together show low rates of iatrogenic
15 addiction. So I think that statement,
16 even though this was 2001, those two
17 articles which I believe were published
18 much later, I don't remember the exact
19 year, confirm. So I think that that
20 statement is correct.

21 Q. Published after 2001 --

22 A. Yes. I think they were
23 after 2010. I don't know the exact
24 dates, the dates are approximate, but I

1 think it was somewhere after -- after
2 that. So a number of years later, that
3 certainly -- the data still seems to
4 support that statement.

5 Q. But what was the support in
6 2001?

7 A. I don't -- I don't know what
8 support FDA would have used to put that
9 in the label.

10 Q. Well, did you agree with the
11 statement back in 2001?

12 A. I did -- well, it was in
13 the -- it was in the label. So I would
14 assume that the evidence would have
15 supported -- substantial evidence or at
16 least an understanding of to have it in
17 the label. So there would have been no
18 reason for me to disagree with the
19 statement at that point.

20 Q. That -- that support would
21 have come from Johnson & Johnson,
22 correct?

23 A. It may have come from --
24 I -- I don't know where this section of

1 the label came from. I don't know
2 whether this was information that was in
3 other product labels at the time. I
4 would need to see those labels to be able
5 to comment on them. Or whether this was
6 information that FDA had derived to
7 make -- so that they felt that this could
8 be put in the label. I don't know the
9 origin of the -- of the language for you,
10 so I can't comment on it at this point,
11 without looking at other product labels.

12 Q. Well, you -- you just told
13 me a few minutes ago that you were doing
14 quality measurements with respect to
15 addiction and abuse, correct?

16 A. Those were done, yes, later
17 on.

18 Q. Okay. And did you have
19 occasion when you were doing those to
20 look at rates of iatrogenic addiction to
21 opioid medications?

22 A. That wasn't -- that was not
23 a primary focus at that time. It was
24 an -- an -- we wanted to understand the

1 types of information that the people who
2 were developing measures were looking at.
3 That was their responsibility. We wanted
4 to see how we could support them. We
5 weren't developing the measures. We were
6 supporting the people and seeing them
7 provide information where we could, as
8 requested.

9 Q. Okay. Are you aware of
10 other studies other than Fishbain and
11 Cochrane?

12 A. Those are the studies that I
13 think looked like at the level of -- and
14 events that were included in those two
15 were high enough quality that I felt
16 comfortable in the conclusions that they
17 drew. There may have --

18 Q. When --

19 A. There may have been other
20 studies to answer your question. But I
21 don't know.

22 Q. When was the last time that
23 you looked at those two studies?

24 A. Actually fairly recently.

1 Q. What's fairly recently?

2 A. Within the last month.

3 Couple weeks.

4 Q. And for what reason were you
5 looking at those two studies?

6 A. Iatrogenic addiction is an
7 area that I'm interested in. And it was
8 something that I wanted to make sure that
9 I was up-to-date on.

10 Q. Were you interested in
11 iatrogenic addiction while you were at
12 Johnson & Johnson?

13 A. I was interested in abuse
14 very much so. I created the -- as I
15 mentioned and gave testimony this
16 morning, I was responsible for helping,
17 working with the company to develop the
18 active surveillance program for our
19 opioid analgesics.

20 Q. Did the active surveillance
21 program concern incidence of addiction in
22 patients taking opioids for chronic pain?

23 A. More abuse than addiction.

24 Q. Okay. But you're interested

1 in iatrogenic addiction for pain
2 patients?

3 A. It's an area of interest of
4 mine.

5 Q. Have you written in it or
6 have you --

7 A. Have I written?

8 Q. Well, let me ask you this.
9 Have you submitted any publications or
10 writings since you left Johnson & Johnson
11 on the subject?

12 A. No, I have not.

13 Q. Are you involved in any
14 clinical studies now with respect to this
15 subject?

16 A. No. I'm not.

17 Q. Are you consulting with
18 anyone with respect to this subject?

19 A. No. But I am interested in
20 addiction in general. And I'm
21 interest -- and I'm looking at ways that
22 I might be able to look at medications
23 that could be used to treat addiction.

24 Q. I see. Did you ever look at

1 any medications for the treatment of
2 addiction while you were at Johnson &
3 Johnson -- Johnson & Johnson?

4 A. I'm sorry. Repeat the
5 question.

6 Q. Did you ever look at any
7 medications, the development or maybe
8 acquisition of any medications for the
9 treatment of addiction while you were at
10 Johnson & Johnson?

11 A. No, I did not.

12 Q. Are you looking at addiction
13 treatments that are drugs or medications
14 or devices or some sort of counseling?
15 Where would it fall?

16 A. Medications, yeah. And not
17 only medications, but also multimodal.
18 Not only -- but also psychological
19 counseling as well.

20 Q. Are you working with anyone?

21 A. Just me.

22 Q. And are these medications
23 that are in development or a medication
24 in development, or is this the use of

1 existing medication?

2 A. Existing medications.

3 Q. And what are they?

4 A. I can't -- it's something
5 that I'm working on now. If I'm allowed
6 to, I prefer not to, because I'm
7 trying -- I'm thinking about potentially
8 seeking a patent for them.

9 Q. Okay. But let me -- let me
10 ask around it a little bit. You are
11 talking about medications that have
12 already been approved by the FDA but you
13 would be seeking an indication that's
14 different?

15 A. Correct. Some of the
16 medications are approved for the
17 treatment of addiction, and I'm looking
18 at some novel combinations. So as part
19 of that interest in addiction in general,
20 I'm also interested in iatrogenic
21 addiction.

22 Q. Have you read Porter and
23 Jick?

24 A. Yes, I have.

1 Q. Okay. What is your analysis
2 of that letter to the editor?

3 A. Well, it was in fact a
4 letter to the editor describing a certain
5 patient population of hospitalized
6 patients.

7 Q. Was it -- you described
8 Fishbain and Cochrane as high quality.
9 Would you --

10 A. Yeah. So I'm sorry. To
11 clarify, so the Fishbain article is one
12 article. The Cochrane review by Roger
13 Chou and other authors as well is the
14 second one. So those are the two
15 articles.

16 Q. Okay. And you consider
17 both -- both of those articles to be of
18 high quality?

19 A. I do.

20 Q. And high quality with
21 respect to the incidence of iatrogenic
22 addiction in chronic pain patients taking
23 opioids?

24 A. By high quality, in the

1 level of evidence of the information that
2 they included from the studies to be able
3 to make the assertions that they -- the
4 conclusions that they had.

5 Q. Did they both of addiction
6 as an endpoint?

7 A. They were looking at rates
8 of addiction and some -- in these
9 patients.

10 Q. And what was the patient
11 population?

12 A. I'd have to go back and look
13 at it. If the articles were here, I
14 could review and comment.

15 Q. I think the Fishbain I'm
16 familiar with is from 1990. Is there
17 something later that you recall?

18 A. This was -- I think this was
19 a more recent article, if memory serves.

20 Q. Do you know if the dataset
21 is more recent or just the article?

22 A. I'd like to look at the
23 articles before I comment.

24 Q. Okay. Well, we'll try and

1 find them.

2 A. Okay.

3 Q. And Cochrane and Chou are
4 the authors?

5 A. No, so Cochrane is -- it's a
6 Cochrane analysis, and there are a number
7 of authors that put together that
8 analysis as part of the Cochrane review.
9 And Dr. Chou is one of the authors.

10 Q. And do you know where that
11 was published?

12 A. In Cochrane. It was a
13 Cochrane analysis.

14 Q. It's just called the
15 Cochrane analysis?

16 A. I don't remember what the
17 title of the study is. We can get is
18 that. But it was published as part of a
19 Cochrane review.

20 Q. Okay. Who sponsored that
21 review? Do you know?

22 A. I'm not sure. I'd have to
23 look and see what they said. This would
24 have been done -- this is -- the

1 Cochrane, as part of the information for
2 Cochrane reviews.

3 Q. Okay. And who -- who
4 sponsored the Fishbain -- Fishbain
5 article?

6 A. I'd have to look and see.

7 Q. You don't know off the top
8 of your head?

9 A. No, I don't.

10 Q. Do you know if Johnson &
11 Johnson ever sponsored Dr. Fishbain?

12 A. I'm not understanding your
13 question.

14 Q. Do you know if Johnson &
15 Johnson or Janssen ever provided any
16 consulting fees or whether Dr. Fishbain
17 was ever a key opinion leader or thought
18 leader or anything for Johnson & Johnson?

19 A. I don't recall.

20 Q. You know what I'm talking
21 about when I say key opinion leader?

22 A. I do.

23 Q. Okay. And you -- as you sit
24 here today, you just don't know if

1 Dr. Fishbain was?

2 A. I know the name. And I know
3 he is a thought leader in the area of
4 analgesia. But I don't know him
5 personally.

6 Q. Okay. Do you know if, while
7 you were at Johnson & Johnson and while
8 you were involved with both Duragesic and
9 Nucynta, whether Dr. Fishbain was ever a
10 key opinion leader or thought leader?

11 A. I don't know if he was.

12 Q. Where does he practice?

13 A. I'm not certain.

14 Q. Have you ever met him?

15 A. I have not. I do not know
16 him personally.

17 Q. How did you evaluate the
18 quality of both the Fishbain article and
19 the Cochrane review, the Cochrane
20 analysis that was in the review?

21 A. So the description in the
22 articles of how they decided what studies
23 to include and what studies to exclude,
24 they talked about why they excluded them.

1 They may not have had -- you know there
2 have been inadequate number of patients
3 or other criteria that they used, were
4 such that they came up with a number of
5 studies, and the criteria seemed
6 reasonable to me to define a high quality
7 of evidence.

8 But, again, in the absence
9 of that, without it in front of me, I
10 would not be able to go into a lot more
11 detail.

12 Q. Yeah, I'm asking you,
13 generally, how you would evaluate the
14 quality of the research in an article.

15 A. So if there are a lot of
16 open label studies. If these studies had
17 a fair number of dropouts. If sometimes
18 the studies don't predefine what their
19 endpoints are before they actually do the
20 analysis, those studies would have --
21 tend to have lower levels of evidence.

22 Studies which were
23 randomized, which would be very
24 important, studies where you predefine

1 the endpoint ahead of time. Certainly
2 studies that are double-blind
3 placebo-controlled would have the highest
4 level of evidence.

5 Those certainly would be the
6 type of studies that would be -- are ones
7 that I would find certainly more
8 impactful and wanted to focus on that
9 type of data.

10 Q. Do you know if there are any
11 double-blind placebo-controlled addiction
12 studies with respect to pain patients,
13 chronic pain patients?

14 A. No. Not that I'm aware of.
15 Those types of studies can be very
16 difficult to conduct.

17 Q. And that's because you would
18 be depriving a pain patient of analgesia,
19 correct?

20 A. Well, you would have to
21 decide how you want to come up with
22 endpoints. So I talked about ACTION
23 earlier. Remember that was the work
24 between FDA and government and industry.

1 And the publication that I
2 participated in, which I think was
3 published in 2013, there may have been
4 one in 2010, they were still trying to
5 define endpoints and how you would define
6 addiction and abuse. So I'm not aware of
7 any -- of the clinical trials that would
8 have been done before that, because here
9 the experts were meeting and trying to
10 understand how to define addiction. And
11 as I mentioned to you, since about 2015 I
12 have not been directly involved in a lot
13 of this.

14 Q. You also oversaw a group of
15 experts that met in 2003, correct --

16 A. Yes.

17 Q. -- to try to attempt to
18 define addiction and abuse and endpoints
19 with respect to those types of studies?

20 A. Correct. That's correct.

21 Q. But you are -- you are
22 satisfied with the definitions of
23 addiction and abuse in Fishbain and the
24 Cochrane analysis?

1 A. I'd have to go back and see
2 what those were done and how they
3 described it. But the question about
4 clinical trials that you had just asked
5 would be to agree on definitions and
6 would be used. And that certainly was
7 still being worked on by the ACTION
8 group.

9 But I'm satisfied with the
10 outcome of the data as described by
11 Fishbain and from the Cochrane review.

12 Q. As you sit here today, you
13 do not know the support for the statement
14 in the 2001 Duragesic label, correct?

15 A. I don't know the origin of
16 the information leading to the statement.
17 Yes.

18 Q. I didn't assume that you
19 would understand the origin. I'm asking
20 you are unaware of the support for the
21 statement?

22 A. Yes, I don't know what
23 information went in to make that
24 statement, yes. Yes.

1 Q. If I wanted to know that at
2 Johnson & Johnson, what support there was
3 for that statement, who would know?

4 A. So what we have been talking
5 about is that this statement may have
6 originated from the FDA. I don't know
7 where it came from. So I don't know -- I
8 don't know whether J&J would have that
9 information or whether this would have
10 been information that FDA had come up
11 with to put this in the label.

12 Q. Well, anything on the label
13 could have been used by a sales
14 representative, correct?

15 A. Yes.

16 Q. To promote the product,
17 correct?

18 A. Yes.

19 Q. And so would you agree with
20 me that if a physician asked a sales
21 representative for Johnson & Johnson what
22 the support was for this statement,
23 regardless of the origin, Johnson &
24 Johnson would have known that support by

1 2001, correct?

2 A. We would have -- we would
3 have been looking to understand where
4 that would have come from, yes.

5 Q. Well, I understand you may
6 be interested in where it came from, but
7 what would be more important would be
8 what the actual support for the statement
9 would be, correct, for the healthcare
10 provider?

11 A. So, if -- if a healthcare
12 provider wanted information on iatrogenic
13 addiction, then the company would have
14 developed a response, an approved
15 response, on the available information
16 from the published literature to support
17 this statement.

18 If you ask me specifically
19 where the support came for the statement
20 in the product label, I don't know
21 whether this was information that was
22 requested by FDA for us to put in based
23 on what they had, or whether this was
24 language that was generated by the

1 company that FDA agreed with.

2 Q. Well, I understand that.

3 And that -- that information will be at
4 Johnson & Johnson, correct, in regulatory
5 or whoever was dealing with the FDA?

6 A. There would be information
7 to support that statement at Johnson &
8 Johnson. It may be in the regulatory
9 group. It may have been information
10 about iatrogenic addiction that would
11 have been -- if it were a question, it
12 would have been -- there would have been
13 support for that from the medical
14 information group.

15 Q. But someone at Johnson &
16 Johnson would have whatever information
17 is the support for that statement?

18 A. There should have been some
19 type of support for that statement
20 somewhere.

21 Q. And as you sit here, you
22 just don't know which group at Johnson &
23 Johnson would have it, but somebody would
24 have it?

1 A. Somebody would have support
2 for that information. So somebody would
3 have published -- or be able to provide
4 information on the published literature
5 to support the rate -- very low rates of
6 iatrogenic addiction.

7 Q. And do you recall ever
8 looking at that data yourself, that
9 published information yourself?

10 A. At that time?

11 Q. At that time.

12 A. No.

13 Q. And what caused you to go
14 to -- later to Fishbain and the Cochrane
15 analysis to look at that data?

16 A. Well, there's a lot of
17 interest in iatrogenic addiction, some of
18 the more recent articles, and again some
19 of the articles that were published. And
20 I'm not familiar completely with the
21 literature, but these are some articles
22 that talk about them.

23 Q. And you just mentioned that
24 there was a lot of interest in iatrogenic

1 addiction. Where did that interest come
2 from?

3 A. My interest?

4 Q. No. You've just mentioned
5 that there's -- "well, there's a lot of
6 interest in iatrogenic addiction." And
7 so I was just curious, where is that
8 interest? Where did you see that
9 interest?

10 A. Well, there's concerns about
11 what's going on with the opioid crisis.
12 People want to understand, so that's...

13 Q. Okay. And when did that
14 begin, that interest in iatrogenic
15 addiction?

16 A. I don't know. I'm talking
17 about my only interest now.

18 Q. Okay. Do you know if there
19 was interest in the rates of iatrogenic
20 addiction at Johnson & Johnson during
21 your tenure with Duragesic and then with
22 Nucynta?

23 A. I don't recall.

24 Q. You don't recall if there

1 was any interest in iatrogenic addiction
2 rates?

3 A. Well, there's no -- I -- I
4 don't know if -- there may have been
5 interest. I just don't recall if there
6 was an interest in it.

7 Q. Did you have an interest in
8 it?

9 A. We -- I was -- I was
10 interested in understanding abuse. There
11 were people were interested in -- we knew
12 that these compounds are addictive. They
13 are Schedule II. So the -- the abuse
14 potential of the compound has already
15 been defined in the law.

16 We were interested in the
17 abuse of the compound and it's relate --
18 I helped, as I've already mentioned and
19 gave testimony this morning, I helped to
20 develop the -- the active surveillance to
21 begin to have a better understanding of
22 that. So there was an interest in
23 understanding abuse of our compound.

24 Q. But you consider abuse to be

1 different than iatrogenic addiction,
2 correct?

3 A. Abuse is -- could be
4 different -- is different from iatrogenic
5 addiction. Iatrogenic addiction is
6 addiction that occurs -- a consequence
7 after receiving a prescription.

8 Q. Do you recall ever making
9 any statements with respect to the
10 expected or predicted rate of iatrogenic
11 addiction?

12 A. I was asked to comment at
13 one time. And the number that I gave was
14 incorrect. I had commented to a -- a
15 member of -- one of our benefit risk
16 group of what I thought rates of
17 addiction were. And I came up with a
18 number which was incorrect.

19 Q. What was that number?

20 A. I believe the number I gave
21 was about 5 percent, or 5 to 8 percent,
22 but that was not correct. That was not
23 iatrogenic addiction. That was addiction
24 in the general population. And I believe

1 that -- that I was talking about rates of
2 alcoholism and other types.

3 So I -- I remember the
4 question. And I remember I -- now, in
5 retrospect, I answered it incorrectly.

6 Q. So when you gave the answer
7 of 5 to 8 percent, you were talking about
8 rates of iatrogenic addiction to
9 controlled substances?

10 A. No. The 5 to 8 percent that
11 I gave was addiction in the general
12 population, like alcoholism, not -- not
13 prescription drugs.

14 Q. Okay. Do you know the rate
15 of iatrogenic addiction to prescription
16 drugs?

17 A. I would have used the
18 information for the two articles that
19 we've been talking about now. And again,
20 it's low.

21 Q. And what -- what is low?

22 A. At the rate of approximately
23 1 to 4 percent or thereabouts.

24 Q. 1 percent to 4 percent?

1 A. Yeah, or thereabouts.

2 Q. Of the population of
3 patients taking opioids for chronic pain?

4 A. Prescribed opioids for
5 chronic pain.

6 Q. But you don't recall what
7 populations those articles looked at?

8 A. I would have to look at them
9 again to comment.

10 Q. And you would consider
11 4 percent to be low?

12 A. I would.

13 Q. Do you know if 4 percent
14 would be rare?

15 A. I think there are
16 definitions that are used for rare for
17 adverse events. And I don't know what
18 those numbers are. I'd have to -- I'd
19 have to look those up.

20 Q. Have you ever heard that
21 rare is less than 1 percent?

22 A. Yes, I would have.

23 Q. Would it be fair to say that
24 4 percent typically would not qualify as

1 rare?

2 MR. LIFLAND: Object to the
3 form of the question.

4 THE WITNESS: I'd have to
5 look and see whether -- there are
6 standard criteria that are looked
7 at. I would want to refer to
8 those before I comment on them.

9 BY MS. CONROY:

10 Q. Okay. And where would I
11 find that standard criteria?

12 A. That may be -- I don't --
13 I'm not -- I don't know if those are
14 published anywhere. But I think FDA has
15 written criteria for what they would call
16 rare -- at least for adverse events as
17 described in their package -- in the
18 package inserts.

19 Q. Do you know if that
20 information is also available at Johnson
21 & Johnson or are there protocols that
22 would discuss that for clinical trials in
23 the evaluation of adverse events?

24 A. I don't know.

1 Q. Is that anything that you
2 ever looked at, would you ever have
3 determined in analyzing data from a
4 clinical trial whether or not certain --
5 a certain type of adverse event was rare
6 or not?

7 A. I would -- I would have had
8 the criteria from the FDA with me to make
9 those determinations. And I don't have
10 those today. And I don't know what they
11 are offhand.

12 Q. Okay. But that's something
13 you would have used?

14 A. That was something that we
15 would have referred to.

16 Q. Okay. The -- did you tell
17 me that the Fishbain article was in 2010?

18 A. No. I said both of those
19 articles were later. I wouldn't -- I
20 don't -- I don't have -- the dates are
21 approximate. I want to say it could have
22 been 2013 or somewhere around there. I
23 didn't have an exact date. That's what I
24 had commented.

1 Q. Okay. I remember a
2 Dr. Fishbain article from 1990. It's not
3 that one, is it?

4 A. No, I believe this was a
5 later article.

6 Q. Okay. Do you know the one
7 I'm talking about?

8 A. I'm not aware of the 1990
9 article. The ones that I took -- the two
10 that I reviewed are the ones that I have
11 been talking about.

12 Q. Do you have copies of those
13 at home?

14 A. I'm not sure. I'd have to
15 check.

16 Q. If -- I know we're going
17 forward tomorrow. So I may ask you to
18 take a -- I will ask you to take a look
19 and see if you have those articles in
20 case we have difficulty finding those two
21 articles.

22 A. I'll look and see if I have
23 it.

24 Q. Okay. They both -- would

1 they both be available as far as you know
2 on PubMed or one of those?

3 A. I don't know. Possibly.

4 Q. How would you find them?

5 A. I -- I don't know if I --
6 how I would dig them up. I don't. But
7 I'll take a look if I have them.

8 Q. Do you have access to PubMed
9 or any of those types of databases for
10 published articles?

11 A. I read them online. And
12 I -- if there are articles that I can't
13 get, I buy them.

14 Q. So you buy them online?

15 A. I -- the articles I have
16 bought online, yeah.

17 Q. Do you know if -- were you
18 involved in the -- I don't have a copy
19 yet so we'll wait.

20 Let's mark the 2008 label.

21 I have no -- I think -- this
22 document has no Bates number. I think I
23 just got it off the web.

24 (Document marked for

1 identification as Exhibit

2 Janssen-Vorsanger-4.)

3 BY MS. CONROY:

4 Q. This is Exhibit 4. This is
5 the approval package for Duragesic,
6 fentanyl. The sponsor is the ALZA
7 Corporation. Do you know what that
8 corporation is?

9 A. Yes, ALZA Corporation.

10 Q. And who is that?

11 A. ALZA Corporation is a
12 corporation that worked with Janssen and
13 ALZA Corporation was purchased by
14 Johnson & Johnson.

15 Q. Then if you turn to Page 26
16 and 27 which is the drug abuse and
17 addiction section.

18 Do you see that?

19 A. Yes.

20 Q. And would you have been
21 familiar with this label on or around
22 2008?

23 A. Yes.

24 Q. And do you recall working

1 with the FDA with respect, or maybe you
2 didn't work directly with the FDA. But
3 do you remember working on the back and
4 forth with the FDA about the language in
5 this label?

6 A. Yes.

7 Q. Then you see on Page 26, the
8 paragraph about addiction.

9 Do you see that?

10 A. I do.

11 Q. And it goes over onto Page
12 27.

13 Do you see that?

14 A. Yes.

15 Q. I no longer see the sentence
16 with respect to iatrogenic addiction. Do
17 you know if that sentence was removed
18 from the label?

19 A. My understanding it was.

20 Q. Okay. And what is your
21 understanding of why it was removed?

22 A. I don't know. I don't know
23 why the label had changed. And that
24 information was no longer present in the

1 label. I'm not -- I don't have
2 information as to why FDA made a decision
3 to remove that from the label.

4 Q. Did you ever ask anyone?

5 A. I did not.

6 Q. Have you ever heard the term
7 pseudoaddiction?

8 A. Yes.

9 Q. Is it a term that you ever
10 used?

11 A. Yes.

12 Q. In what context did you use
13 that term?

14 A. It's a description of people
15 with pain who manifest drug-seeking
16 behavior in an attempt to get better,
17 more effective pain control.

18 Q. Has that ever been tested,
19 that hypothesis that drug-seeking
20 behavior is a result or a consequence of
21 inadequate pain management?

22 A. So patients seek medications
23 for a variety of reasons. There are
24 people who seek medication to abuse, seek

1 medication to divert. But there are also
2 patients who seek medication to control
3 their pain. I'm not aware of any
4 specific study to look at that. But I
5 can say that in the current label, I
6 believe in Duragesic, on abuse, that
7 language is present. Not with the term
8 pseudoaddiction, but that type of
9 behavior is described.

10 Q. Behavior of patients who
11 drug seek to control pain?

12 A. People who seek additional
13 pain medications to try and get -- I
14 believe that's in the section on abuse in
15 the current product label. So the term
16 is not there, but the practice and
17 behavior coined around that term is in
18 the current label to the best of my
19 understanding.

20 Q. Do you know if that
21 hypothesis -- I understand that it's
22 in -- the concept of seeking additional
23 opioid drugs to control pain is in the
24 label. Do you have any knowledge of

1 whether or not that has ever been tested?

2 A. I am not certain of that.

3 No, I'm not certain of that.

4 Q. Have you ever been involved
5 or read any clinical study or
6 investigational study or anything that
7 determined whether or not that hypothesis
8 was true?

9 A. I have observed in clinical
10 practice, but I have not seen it in a
11 study.

12 Q. And what you observed in
13 clinical practice back in Boston was that
14 when a patient was asking for additional
15 opioids, you determined that they were --
16 they were asking because they needed
17 additional pain control?

18 A. It wasn't in Boston. But
19 the idea was correct. It was a patient
20 that presented with a painful condition,
21 and when their pain was under good
22 control, they did not seem -- they did
23 not seek any additional pain medication.

24 Q. And was that -- what was the

1 pain medication?

2 A. It was an intravenous
3 opioid. I don't remember which one.

4 Q. So it was in a hospital
5 setting?

6 A. Yes, that's correct.

7 Q. Have you ever seen it in a
8 clinical setting with a chronic pain
9 patient taking an oral medication?

10 A. No, I have not.

11 Q. And have you ever seen --
12 have you seen any studies or
13 observational reports or anything that
14 validates that drug-seeking behavior for
15 pain control?

16 A. I have not seen such a
17 study.

18 Q. Have you ever read any of
19 the studies concerning AIDS patients and
20 their drug seeking behavior?

21 A. I have not.

22 Q. I'm sorry?

23 A. No, I have not.

24 Q. I may refresh your memory

1 with some of those. Do you remember
2 looking at some of those in the 2003 Ad
3 Board meetings to determine drug-seeking
4 behavior?

5 A. Whether -- I'm sorry. I
6 don't understand your question.

7 Q. Do you recall looking at
8 some AIDS studies with respect to
9 drug-seeking behavior during the 2003 Ad
10 Board meetings?

11 A. There may have been a
12 request for studies to look at that type
13 of behavior. But I don't remember. We
14 received quite a large number of studies
15 that we evaluated and I don't remember
16 all of them at this point.

17 Q. Okay. You can put the label
18 away. Do you know if the label changed
19 again after 2008 for Duragesic?

20 A. I don't know.

21 Q. Doctor, I think I had asked
22 you earlier. You're familiar with key
23 opinion leaders, correct?

24 A. The term?

1 Q. The term.

2 A. I am.

3 Q. And in your role at
4 Johnson & Johnson, you had some
5 involvement in the recruitment of key
6 opinion leaders; is that correct?

7 A. Many of the key opinion
8 leaders were already there. I might have
9 spoken and certainly engaged in
10 discussions with them. I don't know if I
11 recruited people, but I might have.

12 Q. Okay. And what was the --
13 what's the purpose of a key opinion
14 leader?

15 A. To provide information to
16 the company about questions that may come
17 up around our product.

18 Q. And are they also
19 individuals who provide information, not
20 just to the company, but to individuals
21 outside the company about a product?

22 A. They would be -- yes, they
23 would have an opportunity to hear our
24 clinical trial data and provide other

1 information as requested, as well.

2 Q. They would speak to peers
3 about Johnson & Johnson products?

4 A. If they did about J&J
5 products, it would be approved Janssen
6 materials.

7 Q. Well, it would be approved
8 Janssen materials after a particular
9 time, correct? Prior to that,
10 peer-to-peer would not have been -- or
11 are you talking about Janssen approval or
12 FDA approval?

13 A. FDA approval. FDA approval.

14 Q. Okay.

15 A. Yes.

16 Q. So at some point -- we
17 discussed that this morning. At some
18 point, there was a shift and they would
19 be required to use FDA-approved
20 materials?

21 A. Typically though -- yes.
22 Typically, a lot of -- at least the work
23 that I had done, was discussing a lot of
24 our clinical trial data. And some of

1 that -- much of that was pivotal data,
2 data from pivotal studies.

3 Q. And that would have been
4 supplied to the FDA?

5 A. Yes. That would have been
6 as part of the product labeling. Other
7 information could be shared with them as
8 well.

9 Q. But KOLs would provide
10 information to peer groups like at
11 medical CME groups or in-service
12 meetings, things like that?

13 A. Yes, at a time when the
14 companies were still involved in CME,
15 yes.

16 Q. Well, that was -- the
17 company was involved in CMEs at least
18 through 2010. Would that be fair?

19 A. I don't know the date. But
20 yes.

21 Q. Certainly while you were
22 involved with Duragesic?

23 A. Yes. Yes.

24 Q. Do you recall there being

1 involvement with CMEs while you were
2 involved with Nucynta?

3 A. I don't remember. There was
4 a transition time, and I don't recall.
5 It may have. But I don't -- I don't want
6 to speculate. I don't remember.

7 Q. And KOLs are also used to --
8 as authors on publications, correct?

9 A. If they provide -- if they
10 provided analysis and fit the JAMA
11 criteria for being authors, yes.

12 Q. And what's the JAMA
13 criteria?

14 A. They would have had to make
15 significant -- and there are a list of
16 criteria. I'd have to have those in
17 front of me, Counsel, to be able to go
18 through all of them. But very briefly in
19 top line, they would have had to make
20 significant contributions to the work to
21 be an author. They might be involved in
22 the analysis of the data, discussing what
23 types of analysis should be done. They
24 may have involved in running -- but

1 there's a -- there's a list of criteria
2 that we could review. And they would
3 have had to fit those criteria to be
4 eligible to be an author.

5 Q. Okay. And was that criteria
6 required throughout your tenure with
7 Duragesic and Nucynta?

8 A. There was criteria that they
9 had to have active involvement in the
10 study to be put on it. It may not have
11 been all the JAMA criteria. But yeah,
12 they had to make significant
13 contributions to be honest on the paper.

14 Q. So that was a -- that was a
15 Johnson & Johnson criteria?

16 A. Well, they were JAMA
17 criteria, but the company itself had a
18 criteria that they had to make -- they
19 had to make significant input into the
20 article.

21 Q. Was there -- is that in
22 writing anywhere?

23 A. I don't -- I don't know.
24 That's what I -- that's the criteria that

1 I used when I had people on the papers.

2 Q. Did you -- was there any
3 protocol with respect to that at Johnson
4 & Johnson or was that just something that
5 you yourself -- was that a policy of your
6 own or was it broader based than just
7 your policy at Johnson & Johnson?

8 A. I don't recall.

9 MS. CONROY: We'll mark as
10 Exhibit 5.

11 (Document marked for
12 identification as Exhibit
13 Janssen-Vorsanger-5.)

14 BY MS. CONROY:

15 Q. Exhibit 5 is an e-mail
16 chain. The top one dated December 9th of
17 2002. It's JAN-MS-02125643 through 47.
18 And you are free to look through the
19 entire exchange.

20 But I'm going to go to the
21 very first e-mail from you,
22 Dr. Vorsanger, which is on the second to
23 last page.

24 And you say -- you're

1 sending an e-mail to Karen Krasznavolgyi,
2 which I've just butchered that name. But
3 I'm kind of curious if you can pronounce
4 it?

5 A. No.

6 Q. On December 3rd. And the
7 subject line is share of voice request
8 from pain and mycology. What was share
9 of voice if you recall?

10 A. Share of voice, I think,
11 would be the relative contribution, and
12 I'm block -- I don't have a good
13 definition to give you so I'm reaching
14 back now.

15 I think it would be for the
16 amount of the different opioid analgesics
17 that would be in the marketplace.

18 Q. Okay.

19 A. But there -- there are --
20 there may be more precise definitions. I
21 don't have them.

22 Q. And you say, "Hi Karen, I'm
23 taking the lead for pain and mycology."

24 Mycology is -- is fungal

1 infections, correct?

2 A. That's correct.

3 Q. Okay. Did you have -- you
4 didn't have anything to do with that, did
5 you?

6 A. I did not.

7 Q. Okay.

8 "On understanding
9 Duragesic's share of voice in the market
10 of long-acting opioids. To better
11 understand this, we are interested in
12 defining the key journals where
13 publications on either Duragesic,
14 Percocet, or OxyContin may be found."

15 So those three, Duragesic,
16 Percocet and OxyContin, would you
17 consider those to be long-acting opioids?

18 A. Percocet, no. Duragesic and
19 OxyContin, yes.

20 Q. Okay. And you are asking
21 her -- you -- if you look further on, you
22 want her to go back no more than five
23 years. And you're not looking for the
24 specific publications, but rather the

1 journals where articles were published
2 about those three drugs, correct?

3 A. Yes.

4 Q. And then if she did her job,
5 you would get a list of the major
6 journals where papers related to these
7 products are published, correct?

8 A. Yes.

9 Q. And do you recall why you
10 wanted to know that?

11 A. Well, this was early on.
12 And I had started at Janssen in 2000.
13 And wanted to understand the types of
14 journals that -- where these types of
15 publications would take place, and then
16 understand. So as we began to do our --
17 and I'm kind of reaching back to think
18 about what I might have meant by share of
19 voice. Here I think it was a publication
20 share of voice, not a market share of
21 voice, to decide what types of -- where
22 the journals we should be publishing --
23 where the places that people who --
24 prescribers who treat pain, what are the

1 types of articles, where are they being
2 published, so we could -- we could be
3 current with them.

4 Q. And you wanted to be -- is
5 it fair to say that you wanted to at
6 least have as much of a presence in those
7 journals as your competitors?

8 A. We wanted to have a presence
9 in the journals that -- of where the
10 people who prescribe pain medications
11 read, yes.

12 Q. And that was because you
13 would be able to oversee publications and
14 assist getting those publications or get
15 articles published in those journals?

16 A. Those would be journals
17 where -- where our clinical studies we
18 would submit to see if we could get those
19 published.

20 Q. And that would be
21 company-sponsored clinical studies as
22 well as investigator studies?

23 A. So the
24 investigator-initiated studies, when I

1 was involved in that, we would reach out
2 to them and ask them where they would
3 like to publish their work. The
4 company-sponsored studies, we wanted to
5 make sure that we were having our studies
6 published in some of the top tier
7 journals where the most people who get --
8 who are involved in pain management would
9 be reading those. This is an idea of
10 seeing where do people tend to publish.

11 Q. And would you be writing
12 those articles yourself, would you get
13 medical writers involved or would some of
14 the authors on the study be actually
15 writing the article?

16 A. So I wrote some of the
17 articles. I would co-write with some of
18 the other authors on the articles, and
19 some of the articles that perhaps would
20 be written by medical writers. We would
21 be involved in organizing the data.
22 Instructing what should be put in there.
23 How it would be done. And then working
24 through with them until the article was

1 published so...

2 Q. And would you have a list of
3 subject areas where you would like
4 articles to be written?

5 A. Well, for the clinical trial
6 data from the primary studies, we would
7 just publish the studies. If there were
8 other areas of interest that we wanted to
9 reach out then we would come up with
10 that. That would be part of our
11 publication plan, yes.

12 Q. And did you have a budget
13 for that publication plan?

14 A. There was a budget.

15 Q. And who would develop that
16 budget?

17 A. I don't know who developed
18 it. I was told about how much money I
19 had to spend.

20 Q. Okay. And then that -- then
21 you would follow that budget?

22 A. Yes.

23 Q. Do you know if marketing was
24 involved in that budget?

1 A. The decisions for where the
2 publications would go would have been
3 done through U.S. medical affairs. And I
4 don't know -- I don't know.

5 Q. Okay. If you look at the
6 individuals that are on this first
7 e-mail, were they all in your department
8 or what department was Karen in or Donna
9 or Surya?

10 A. So Surya was in my
11 department. I don't know who Karen K. is
12 anymore. I don't recall. And Donna
13 Haura, I forget where she is.

14 Q. Was she in your department
15 do you know?

16 A. I don't think so. But I
17 don't remember where she was.

18 Q. Do you have any recollection
19 of -- if you take a look at the second
20 page at the very bottom. I'm looking at
21 644. It says, "From the list" -- very
22 last sentence, "From the list by far the
23 most articles were printed in the
24 'Journal of Pain and Symptom Management'

1 with a total of 118 references."

2 Do you see that?

3 A. Mm-hmm, mm-hmm.

4 Q. Do you recall that journal?

5 A. Yes.

6 Q. And do you know who
7 published that journal?

8 A. I don't recall.

9 Q. Have you ever been published
10 in that journal?

11 A. I have.

12 Q. We can put that one away.

13 Mark as Exhibit 6.

14 JAN-MS-02267733 through -- that might --
15 oh, and it's -- what's attached is a
16 native which is JAN-MS-02267734, with --
17 which is a five-page -- looks like a
18 PowerPoint.

19 (Document marked for
20 identification as Exhibit
21 Janssen-Vorsanger-6.)

22 BY MS. CONROY:

23 Q. The top is an e-mail dated
24 July 21, 2011, to Charles Oh and yourself

1 from Myoung Kim. Do you see that?

2 A. Yes.

3 Q. And the -- attached are some
4 Nucynta BP slides. Do you see that?

5 A. Oh yeah.

6 Q. What is a BP?

7 A. This is from --

8 Q. What department was Myoung
9 Kim in?

10 A. So Myoung Kim was in
11 outcomes research. But she then moved
12 over to be a therapeutic area leader for
13 analgesia. And Charles Oh and I reported
14 into her.

15 Q. Okay. So she --

16 A. She was in medical affairs
17 at this point.

18 Q. Okay. And you reported to
19 her?

20 A. Correct.

21 Q. Oh I see. Actually we have
22 her title right there.

23 Now this has a 2012 business
24 plan for Nucynta and Nucynta ER.

1 A. Yes.

2 Q. ER is extended release?

3 A. Correct.

4 Q. And would you have been
5 involved in the drafting of this business
6 plan or the oversight?

7 A. I would have provided some
8 information on what we had heard from
9 prescribers about the types of
10 information that they were deemed --
11 deemed to be scientific and medical
12 information that would be important for
13 the product.

14 Q. Okay. And some of those --
15 or let me ask you. The first block here
16 says, "Establish Nucynta as new standard
17 in moderate/severe pain management."

18 Do you see that?

19 A. Yes.

20 Q. And that was a strategic
21 imperative for the business, correct?

22 A. Some of this -- yes. But
23 this may have been what people would like
24 to have, yes. Some of these would be

1 aspirational.

2 Q. Okay.

3 A. Yeah.

4 Q. And so if this was an
5 aspirational imperative, one of the ways
6 to get there would be the strategic
7 drivers, right? Do you see that on the
8 side?

9 A. Yeah, that would be
10 important, yes.

11 Q. Okay. And to -- in order to
12 establish Nucynta as a new standard in
13 moderate to severe pain management, you
14 would want to, "Leverage significant SOV
15 to accelerate penetration/productivity
16 with target healthcare professionals and
17 sites of care (institutions and long-term
18 care facilities)."

19 Do you see that?

20 A. Yes.

21 Q. And what does SOV mean?

22 A. Share of voice.

23 Q. So you would want to have at
24 least as much presence in publications as

1 your competitors to be able to leverage
2 penetration and productivity with respect
3 to healthcare professionals and sites of
4 care, correct?

5 MR. LIFLAND: Object to the
6 form of the question.

7 THE WITNESS: We would want
8 to have appropriate information
9 published and be available to
10 individuals who were treating
11 patients to be able to be
12 knowledgeable enough about the
13 safety and efficacy of the
14 compound, to make and to use for
15 appropriate use in patients.

16 BY MS. CONROY:

17 Q. And it would be important to
18 get that information published so it got
19 out to target HCPs and sites of care,
20 correct?

21 A. Yes.

22 Q. So one method, one driver
23 would be publications, correct?

24 A. One method would be to make

1 sure that the available clinical data and
2 studies were available for these
3 individuals to review and make the
4 decisions about whether our products
5 would be appropriate for their patients.

6 Q. Right. And one of the
7 strategic drivers would be such
8 publications?

9 A. Ensuring that we have
10 publications.

11 Q. And then another driver
12 would be to, "Grow brand awareness
13 through print and online media."

14 So that would be electronic
15 publications as well, correct?

16 A. Presumably.

17 Q. Third driver is,
18 "Competitively differentiate versus
19 current standard of care (oxy)."

20 What's that getting at?

21 A. To provide information --
22 again, we wanted to make sure that our
23 products were used for appropriate
24 patients who use as prescribed. And to

1 provide information to understand where
2 the products may be similar and where the
3 products may be different, so that
4 healthcare providers could make informed
5 choices as to which drugs to use for
6 their patients.

7 Q. But you were looking -- one
8 of the drivers would be to differentiate
9 yourself from oxy, correct?

10 A. Well, the differentiation
11 would be to show the attributes of both
12 compounds to be able to have
13 non-prescribers understand why you would
14 choose one compound over another
15 compound.

16 Q. And would one attribute be
17 potentially less abuse risk?

18 A. Abuse was not something that
19 was discussed in a promotional venue.

20 Q. Why is that?

21 A. Because the level of
22 evidence, the types of studies that the
23 company had that discussed about abuse
24 were not sufficient to be used in

1 promotional materials according to FDA
2 standards.

3 Q. So it would be wrong to
4 discuss abuse propensity or abuse rates
5 or any -- any type of differentiation
6 between products with respect to abuse?

7 MR. LIFLAND: Object to the
8 form of the question.

9 THE WITNESS: Could you
10 rephrase? I'm not sure I
11 understand your question.

12 BY MS. CONROY:

13 Q. Sure. You said because --
14 you said abuse was not something that was
15 discussed in a promotional venue?

16 A. Proactively, yes.

17 Q. Proactively. What does that
18 mean, proactively?

19 A. If a question came up, the
20 sales force -- then the sales force
21 would -- the company standard was that
22 the sales force were instructed to refer
23 those questions to the medical
24 information group. And the medical

1 information group is a group of mostly
2 pharmacists and PharmDs and there would
3 be company-approved letters that could be
4 used.

5 Q. With respect to abuse?

6 A. Yes.

7 Q. Okay. But in the -- in the
8 promotional venue, you could not discuss
9 abuse because you didn't have the
10 level -- you didn't -- you say because
11 the level of evidence of the types of
12 studies that the company had that
13 discussed about abuse were not sufficient
14 to be used in promotional materials,
15 according to the FDA.

16 A. Correct. The materials that
17 described abuse were from the RADARS
18 publications and from the Inflexxion
19 publications.

20 Q. And those were not
21 sufficient -- the RADARS and the
22 Inflexxion publications were not
23 sufficient according to the FDA to use in
24 promotional materials with respect to

1 abuse, correct?

2 A. That would -- that was the
3 company's thinking.

4 Q. And so if someone did that
5 from Johnson & Johnson, Janssen, with
6 respect to Duragesic or Nucynta, that
7 would be wrong?

8 MR. LIFLAND: Object to the
9 form of the question.

10 THE WITNESS: We would need
11 to understand a venue and what it
12 happened and how and what the
13 nature of the conversation. I'm
14 not able to address it in a
15 blanket statement. I would need
16 to understand the circumstances.

17 BY MS. CONROY:

18 Q. Well, the circumstances
19 would be using RADARS or Inflexxion data
20 in a promotional venue.

21 A. The materials that were
22 prepared by the company for promotional
23 use did not have either RADARS or
24 Inflexxion data in those materials.

1 Those are the approved materials that
2 Janssen created, did not have those data
3 in there.

4 Q. And so if that data was
5 used, it would be in violation of the FDA
6 standards?

7 A. I would need to understand a
8 little bit more on the circumstances
9 under how they were used. But there were
10 not company -- they were not included in
11 company-approved materials.

12 Q. What more would you need to
13 know?

14 A. You said if they were used,
15 I would understand -- how were they used?
16 Under what circumstances were they used?

17 Q. If -- if a sales
18 representative was using the data from
19 Inflexxion or RADARS in a promotional
20 venue, would that be --

21 A. How would -- how would that
22 happen, Counselor?

23 Q. I'm sorry?

24 A. How would that -- how would

1 that happen? They would not be using
2 approved materials. I'm trying to
3 envision what it would look like.

4 Q. So that could never happen?

5 A. It would not be a
6 company-approved or a company-condoned
7 activity.

8 Q. And if a sales
9 representative did say something in a
10 promotional venue about Inflexxion or
11 RADARS data, that would be a violation of
12 the FDA standards?

13 MR. LIFLAND: Object to the
14 form of the question.

15 THE WITNESS: I would need
16 to understand the circumstances
17 under which that happened.

18 BY MS. CONROY:

19 Q. Under what circumstances --

20 A. Well, if a sales
21 representative, for example, said, "The
22 company monitors abuse using these two
23 systems," there's nothing wrong with
24 that. They are not talking about data.

1 So I would need to understand the nature
2 of the conversation that took place
3 between the healthcare provider and the
4 sales representative to be able to answer
5 that question. I can't give you a
6 blanket answer. I would need to
7 understand the circumstances under which
8 that took place.

9 Q. Is that the answer that you
10 would give to a sales rep if they asked
11 that question? If a sales rep said to
12 you, "Is it okay for me to use data from
13 RADARS and Inflexxion when I'm in a
14 promotional venue?" would you say, "I
15 need to understand exactly what you were
16 saying"?

17 A. No. The sales rep -- the
18 sales rep were trained on using approved
19 materials. So that question should not
20 have come up. If you're a salesperson,
21 you say, "Here are the company-approved
22 materials. This is what you're going to
23 use to sell the product."

24 Q. And if a sales

1 representative goes outside of the
2 approved sales materials, that's a
3 violation of the FDA standards, correct?

4 MR. LIFLAND: Object to the
5 form of the question.

6 THE WITNESS: If the -- if
7 the sales representative uses
8 non-company-approved materials.
9 And it's not a -- it's not a
10 behavior that's approved by the
11 company.

12 BY MS. CONROY:

13 Q. Or by the FDA?

14 A. I would have to find out
15 specifically what -- yes.

16 Q. And Inflexxion and RADARS
17 data were not approved company materials
18 that could be used for promotion,
19 correct?

20 A. The data -- the data that
21 were contained from those were not part
22 of the promotional materials that the
23 company used.

24 Q. Could you competitively

1 differentiate Duragesic or Nucynta from
2 oxy based on addiction rates?

3 A. Not by the data that we used
4 in a promotional venue.

5 Q. Were you able to use any of
6 the Fishbain or Cochrane analysis data
7 for promotional materials?

8 A. I'd have to go back and look
9 at the promotional materials at the time
10 to see.

11 Q. You don't recall?

12 A. I don't recall that those
13 would have been studies that would have
14 been part of it.

15 Q. Do you know if any of the
16 data from any of the clinical trials that
17 were performed as -- that became part of
18 the Cochrane analysis for Fishbain's
19 article were ever submitted to the FDA?

20 A. I don't know.

21 Q. Is that anything that you've
22 ever looked at? Do you think you ever
23 knew that?

24 A. Well, the two articles that

1 I referenced would have been later on.
2 We talked about those as being later on.
3 2010, 2013. So that would have been
4 after the time that I might have been --
5 well, I would have been out of
6 promotional review committee. No. Up
7 until '15 I don't remember seeing those
8 articles. That doesn't mean they weren't
9 used. I just don't remember.

10 Q. Okay. And a separate
11 question. Do you recall when you looked
12 at those articles whether -- and the
13 analysis, whether or not any of the
14 clinical trials used in those articles
15 had been -- had been submitted to the
16 FDA?

17 A. So those studies I've looked
18 at more recently. I don't recall seeing
19 them earlier. So I can't comment. I
20 don't know.

21 Q. You don't have a memory as
22 you sit here today of those two -- the
23 article and the analysis coming through
24 the promotional review board?

1 A. I don't have a memory of
2 that.

3 Q. The next strategic driver
4 is, "Execute leading edge on label,
5 peer-to-peer education options to
6 complement personal promotion."

7 Do you see that?

8 A. I do.

9 Q. What does that mean?

10 A. I'm not sure.

11 Q. Peer-to-peer education would
12 be what you described to me before,
13 peer-to-peer between medical or
14 scientific-credentialed individuals at
15 the company with like individuals outside
16 the company?

17 A. Yes.

18 Q. What's personal promotion?

19 A. That's what I'm not sure of.

20 Q. And the last one on this one
21 is, "Deploy differential resourcing to
22 drive local market opportunities."

23 Do you see that?

24 A. Yes.

1 Q. Do you know what
2 differential resourcing is?

3 A. I do not.

4 Q. Do you know who would know
5 that? What -- what department at Janssen
6 would know the answer to that?

7 A. I'm not sure.

8 Q. So are these marketing
9 terms?

10 A. Yeah, I'm not sure.

11 Q. It -- it says it's the
12 tapentadol market strategy. So would --
13 would it be a fair assumption to assume
14 that someone in marketing would
15 understand what was here?

16 A. I guess so. I don't know.
17 These are not terms that I'm -- that I'm
18 familiar with.

19 Q. Then the next strategic
20 imperative is to "drive broad and
21 competitive access and availability."

22 Do you see that?

23 A. I do.

24 Q. That's access and

1 availability of tapentadol or Nucynta,
2 correct?

3 A. Yes.

4 Q. And so that -- that's to be
5 sure that if a patient has a prescription
6 for Nucynta, that they are able to fill
7 it, correct?

8 A. Right.

9 Q. And then under the strategic
10 drivers, it says, "Secure T2 formulary
11 access in targeted commercial and Part D
12 accounts."

13 Do you see that?

14 A. I do.

15 Q. T2 is Tier 2, correct?

16 A. I believe so. These are
17 marketing activities, so it -- I would
18 refer a lot of these to someone from the
19 marketing group who could probably
20 explain these better than I can as a
21 medical person.

22 Q. Okay. Do you have a general
23 understanding of the tiers in formulary
24 access?

1 A. I do not.

2 Q. Okay. Do you understand
3 Part D Medicare?

4 A. No, I don't.

5 Q. Not many people do, so...

6 Next one is "accelerate
7 regional pull-through of national
8 formularies."

9 Are you familiar with
10 national formularies?

11 A. I -- yeah, no these are --
12 it's -- it's not an area -- I know what a
13 formulary is, but I don't know the
14 context as it's written here.

15 Q. Okay. The next one,
16 "Patient saving programs." Do you know
17 anything about those?

18 A. Those would be marketing
19 activities.

20 Q. "Stocking and formulary
21 access"?

22 A. Same.

23 Q. "Ensure widespread pharmacy
24 stocking of all dose strengths"?

1 A. Marketing related
2 activities.

3 Q. Okay. The next strategic
4 imperative is "demonstrate industry
5 leadership in advocacy for healthcare
6 providers and patient access."

7 Do you see that?

8 A. Yes.

9 Q. And would this be
10 organizations such as American Academy of
11 Pain Management, American Academy of
12 Pain -- what's the other one? Management
13 and maintenance or -- pain medicine,
14 those types of organizations?

15 A. I'm not exactly sure what
16 this is meant by. I don't know if this
17 is advocacy just on the company, or
18 advocacy, working with advocacy groups.

19 The -- the third bullet I
20 think -- it just says, "Collaborate with
21 key patient advocacy organizations to
22 advance awareness of the undertreatment
23 of pain."

24 I -- I don't know exactly

1 what advocacy means in this reference.

2 Q. Are you familiar with any of
3 the key patient advocacy organizations?

4 A. I had some familiarity when
5 I worked with them years ago, but I don't
6 remember what they did and our
7 interaction with them today.

8 Q. Do you recall Partners
9 Against Pain?

10 A. I heard the term, but I
11 don't remember the -- I don't remember in
12 what context.

13 Q. Was that anything, even if
14 you don't remember the actual groups
15 today, was that anything that you would
16 have had involvement in, in your
17 day-to-day responsibilities?

18 A. Not directly. If there were
19 materials that went for promotional
20 review, I might have seen it. But
21 otherwise I -- I just simply don't
22 recall.

23 Q. Okay. The last one there is
24 "influence development of quality

1 measures in pain."

2 Is that pain scales and the
3 like?

4 A. Equality measures we talked
5 a little bit about earlier, the types of
6 things that would be important to
7 patients and healthcare providers as
8 measurements that would be used as a
9 broadbase. So that we -- there was a
10 uniform agreement for example, that
11 everybody would use pain measures or
12 other types of -- you know, identifying
13 and soliciting adverse events and other
14 types of quality measures that were being
15 put, ensuring good levels for pain
16 control, et cetera.

17 Q. Okay.

18 The second bullet point. Do
19 you know what an HPAD or SGA is? Where
20 it says, "Develop national pain policy
21 platform to align local efforts of HPAD
22 and SGA"?

23 A. I don't -- I don't know what
24 the terms are today. I don't recall what

1 they might have stood for.

2 Q. Okay. And then the fourth
3 strategic imperative is, "Strengthen
4 differentiation and value through new and
5 compelling evidence."

6 Do you see that?

7 A. I do.

8 Q. Differentiation is how
9 Nucynta differs from its competitors,
10 correct?

11 A. Yes.

12 Q. Then the bullets here are,
13 "Generate new data for superior
14 effectiveness."

15 Do you see that?

16 A. Yes.

17 Q. That would be a clinical
18 study?

19 A. Yes.

20 Q. And it would have to be,
21 correct, in order to use that in a
22 promotional venue?

23 A. Yes.

24 Q. And it would need -- that

1 data would need to go to the FDA?

2 A. In order to be used
3 promotionally, it would have to fit the
4 FDA criteria.

5 Q. Okay. And in order to
6 differentiate between one drug, between a
7 competitor, and Nucynta, the clinical
8 study would need to be a head-to-head
9 study, correct?

10 A. In order for it to have an
11 adequate level of evidence it would have
12 to be a study that would comport with an
13 FDA requirement for that specific area.

14 Q. Okay. So if you wanted to
15 say Nucynta was more effective in pain
16 relief than OxyContin for example, the
17 clinical study would have to measure both
18 of those?

19 A. Both of those would have to
20 be active comparators in the --

21 Q. In the --

22 A. In the clinical trial.

23 Q. In the study?

24 A. Yeah.

1 Q. "Filling data gaps, label
2 enhancement."

3 What does that mean?

4 A. I think to ensure that the
5 label has the most up-to-date information
6 about the products. Those would be based
7 on -- in conversations with the FDA, to
8 ensure that -- that that data as
9 appropriate would be available at least
10 for discussion to see if it could be put
11 in the label.

12 Q. And that would, and we
13 talked about this earlier this morning,
14 that would also include safety
15 information or any concerns about the
16 drug, correct?

17 A. If FDA had warranted and
18 decided that that would be appropriate
19 for dissemination to healthcare
20 providers, yes.

21 Q. But as we -- as we spoke
22 this morning, there is nothing to prevent
23 J&J from bringing safety concerns to the
24 FDA?

1 A. Absolutely.

2 Q. "Lower abuse potential." Do
3 you see that?

4 A. I do.

5 Q. Was there an effort to find
6 new and compelling evidence with respect
7 to lower abuse potential?

8 A. Some of this may refer to
9 looking at the abuse deterrent
10 formulations that we might be talking
11 about as one.

12 Q. Did Nucynta ever receive an
13 abuse deterrent formulation indication
14 from the FDA?

15 A. No. We had -- the Nucynta
16 ER has an abuse deterrent system, but
17 the -- the types of studies that were
18 needed to be done to be able to do that
19 were studies that were not clear.

20 I had gone to FDA to ask the
21 question of what types of studies would
22 need to be done.

23 Now our data from a variety
24 of sources, including our own

1 pharmacovigilance data and data from
2 RADARS and others, showed low mentions of
3 abuse in our immediate release
4 formulation.

5 So with the extended-release
6 formulation, in order to be able to show
7 a reduction in abuse was challenging
8 because the amount of abuse that we had
9 seen in the immediate release was low.
10 So if you're asking to put a formulation
11 in place to reduce it on an already low
12 level of abuse becomes challenging. So
13 when that question -- we raised that
14 question with FDA and FDA said we need to
15 think more about that.

16 Q. So at least as of 2012,
17 lower abuse potential, even though you
18 were seeing dose -- very low levels in
19 the RADARS and maybe even the Inflexxion
20 data, that could not be used for
21 promotion?

22 A. Correct. But it would be
23 used if a -- if a healthcare provider
24 wanted the information on abuse, that

1 type of information, there -- there was a
2 company-approved letter. So that maybe
3 the information might have been
4 disseminated in those letters.

5 But I'd need to see those
6 letters to see what type of information
7 was actually contained.

8 Q. And the healthcare
9 professional would need to -- to ask and
10 then the letter would come from J&J,
11 correct?

12 A. It would come from the
13 medical information group at J&J. But
14 the -- the card would have been -- so the
15 sales representative wouldn't have
16 fielded the question. It would have sent
17 the card into the company and in response
18 to that request, the company would have
19 provided a letter, yes.

20 Q. Okay. "MOA
21 differentiation."

22 What does that mean?

23 A. MOA I'm -- here, I'm
24 assuming, is mechanism of action.

1 Q. And is that the discussion
2 between the -- the dual mechanism of
3 action that was available with Nucynta?

4 A. That -- the -- based on
5 animal studies?

6 Q. Correct.

7 A. That the -- in the product
8 label, they talk about dual mechanism of
9 action. And that that dual mechanism of
10 action would be different from the -- the
11 opioid analgesia as described on some of
12 the other opioids.

13 Q. And the hypotheses was that
14 the dual mechanism of action would
15 potentially lower the abuse potential?

16 A. The hypothesis is that the
17 dual mechanism -- the hypothesis was that
18 the dual mechanism of action was such
19 that the analgesia was given both from
20 the norepinephrine reuptake inhibitory
21 properties as well as from the opioid
22 receptor properties.

23 Q. And the -- the upshot of
24 that is there would be potentially less

1 euphoria, and consequently less abuse
2 potential?

3 A. The hypothesis was that that
4 might be a reason.

5 Q. Okay. That was never
6 proven, correct?

7 A. It wasn't proven, but we did
8 it here in the early days when the
9 immediate release formulation first came
10 to market, that we had reports from
11 healthcare providers that they initially
12 thought that the product didn't work and
13 when we went back and had them check pain
14 scores, the patients were experiencing a
15 reduction in pain intensity, but they
16 didn't experience some of the euphoria.
17 So those were some of the earlier things
18 that we had heard about in the immediate
19 release formulation.

20 Q. Was it expected that
21 patients in an extended-release -- let me
22 ask you this. Did the extended-release
23 have the dual mechanism of action?

24 A. Yes. So the

1 extended-release was the same compound.
2 It was tapentadol, but it was put in this
3 formulation that it would slow the
4 release. That's why it was
5 extended-release.

6 Q. But it was still a dual
7 mechanism?

8 A. Yes. Believed to be, based
9 on animal studies, correct.

10 Q. Is Duragesic a dual
11 mechanism?

12 A. It is not. Duragesic is --
13 provides analgesia. It's believed to
14 provide analgesia mostly from the
15 opioid -- from its primary -- its opioid,
16 direct opioid effect.

17 Q. And were there reports of
18 euphoria with Duragesic versus less
19 euphoria with the immediate release
20 Nucynta?

21 A. So, I don't have comparator
22 statement. I didn't hear that one drug
23 had more euphoria than another one. We
24 just heard from the field anecdotally

1 that there were patients that reported
2 receiving less euphoria.

3 I'd like to take a break.

4 Q. Let me just -- we can finish
5 this document if you've got two minutes?

6 A. Okay.

7 Q. Okay. The mechanism of
8 action differentiation, that was not
9 something that could be promoted,
10 correct?

11 A. The mechanism of action was
12 something that if people wanted specific
13 information on it, they would write --
14 they would have to go through the process
15 that I already described through medical
16 information.

17 Q. If they went through that
18 process, was it -- was it all right for
19 Johnson & Johnson to respond that the
20 mechanism of action, that there was a
21 hypothesis that that would lower abuse
22 potential?

23 A. I don't believe that was in
24 the letter. I would have to look at the

1 letter to comment on that, Counsel.

2 Q. Okay.

3 A. But there was a potential
4 hypothesis. Again, that hypothesis was
5 not used as far as I know in promotional
6 interactions.

7 MS. CONROY: Let's take a
8 break.

9 THE VIDEOGRAPHER: Stand by,
10 please. Remove your microphones.
11 The time is 3:05 p.m. Off the
12 record.

13 (Short break.)

14 THE VIDEOGRAPHER: We are
15 back on the record. The time is
16 3:24 p.m.

17 BY MS. CONROY:

18 Q. Doctor, the document you
19 have in front of you, you see that the
20 last strategic imperative has some red
21 outline around the top where it says,
22 "Strengthen differentiation and value
23 through new and compelling evidence"?

24 A. Yes.

1 Q. Do you see that?

2 And if you turn the page to
3 the next, Page 3 of the -- it's probably
4 a PowerPoint. You'll see that that's
5 across the top, "Strengthen
6 differentiation and value through new and
7 compelling evidence."

8 Do you see that?

9 A. Yes.

10 Q. And then above that it says,
11 "MA and HECOR strategic drivers and
12 proposed studies."

13 Do you see that?

14 A. Yes.

15 Q. Is MA medical affairs?

16 A. Yes.

17 Q. And what is HECOR?

18 A. It's health economics and I
19 don't remember what it is. This would
20 have been another name for the outcomes
21 research group.

22 Q. Okay. So these are the --
23 these are the areas you would know
24 something about, correct?

1 A. Yes. This would be work
2 that would be done by either the medical
3 affairs group or the outcomes research
4 group, yes.

5 Q. Okay. So the strategic
6 driver of superior effectiveness, that
7 Nucynta worked better than other opioids,
8 the primary audience for that would be a
9 physician, do you see that?

10 A. Yes.

11 Q. And then the proposed study
12 was a superiority trial of
13 immediate-release Nucynta versus
14 OxyContin in osteoarthritis or lower back
15 pain. Do you see that?

16 A. Yes.

17 Q. Do you know if that trial
18 was done?

19 A. I don't believe the study
20 was done. I don't believe that we had
21 conducted a superiority trial. But it
22 was certainly proposed.

23 Q. Okay. Do you know why it
24 was not done?

1 A. I don't remember.

2 Q. Do you know if it was
3 started?

4 A. I don't think so. But I'm
5 not sure. But I don't think so.

6 Q. Where would records be with
7 respect to whether or not that study was
8 started?

9 A. It would be in the --
10 certainly would have been in the medical
11 affairs files.

12 Q. Okay.

13 A. But this would have been a
14 study that I might have been involved in
15 conducting and I don't recall us doing
16 that type of a study.

17 Q. Okay. The next one is the
18 "filling the data gaps, label
19 enhancement." We talked a bit about that
20 a few minutes ago.

21 A. Yes.

22 Q. That audience would likewise
23 be a physician?

24 A. Yes.

1 Q. You agree with that?

2 A. Yes.

3 Q. What's a switching trial?

4 A. A switching trial would have
5 been on a patient being treated with one
6 opioid pain medication and switching to
7 another one.

8 Q. And what's a high dose
9 trial?

10 A. That would be looking at
11 potentially higher doses in patients
12 above what would be on the product label,
13 but those would require well-controlled
14 studies submitted to FDA. And in
15 parentheses, PRD means that those studies
16 would have been done by our research and
17 development group, not the medical
18 affairs group.

19 Q. Okay. That's because they
20 would potentially be off-label?

21 A. No. It would be because
22 studies that were used for product
23 approval would be -- initial approval
24 would be done by -- at Janssen would be

1 done at the R&D group. We talked earlier
2 that medical affairs was responsible --
3 responsible for postapproval studies, and
4 since this would have been for a label
5 change with a new dose, this would have
6 been data submitted to FDA, and the
7 studies would have been done through that
8 group.

9 Q. Okay. Was the switching
10 trial ever done?

11 A. The patients would have been
12 on one drug and switched over to another
13 one. May -- it could have been whatever
14 the company was thinking about at the
15 time. It could have been OxyContin to
16 Nucynta. It could have been OxyContin to
17 Nucynta and then another arm Nucynta to
18 OxyContin, a variety of different
19 studies. But you would switch from one
20 drug to another.

21 Q. Do you know if that
22 switching trial was ever done?

23 A. I don't think so, but I'm
24 not sure.

1 Q. Okay. Do you know if -- do
2 you know if R&D ever did the high dose
3 trial?

4 A. No. I don't think so.
5 Given that the highest doses are still
6 the same as in the package insert that
7 they were at product approval, they were
8 not -- we didn't have a study with new
9 data that would have informed the package
10 insert.

11 Q. Okay. The strategic driver
12 of lower abuse potential, that audience
13 would be both the payer and the
14 physician.

15 Do you see that?

16 A. Yes.

17 Q. The first bullet point is,
18 "The Nucynta abuse potential (NAP) task
19 force 2011 to map out the master plan."

20 Was there a Nucynta abuse
21 potential task force?

22 A. Not that I recall.

23 Q. Do you know if there was
24 ever an abuse potential trial comparing

1 Nucynta ER versus OxyContin? Do you know
2 if that was ever conducted?

3 A. No, not that I'm aware of
4 postapproval.

5 Q. Would you be the person that
6 would be aware if that was done?

7 A. I would have heard about it.

8 Q. Okay. Do you know why that
9 was not done?

10 A. No, I don't.

11 Q. The drug likability trial
12 versus OxyContin. Do you know if that
13 was done?

14 A. I'm not sure if we had done
15 this, if the study was done with
16 comparing people who were used to abusing
17 those drugs. There may have been a
18 study, but I'm not sure.

19 Q. Drug likability is with
20 respect to whether addicts like to use a
21 particular drug over another --

22 A. Yes.

23 Q. -- for abuse?

24 A. Yes. There may have been

1 such a study, but I don't -- I just don't
2 remember.

3 Q. If there was, would you have
4 been involved in it?

5 A. I might have heard about it,
6 yes.

7 Q. I think this means to be
8 RADARS, right?

9 A. It's a typo, yeah.

10 Q. Okay. And "NAVIPPRO and
11 other observational studies."

12 Do you see that?

13 A. Yes.

14 Q. And RADARS is a surveillance
15 program?

16 A. Yes, that's right.

17 Q. And what is NAVIPPRO?

18 A. It's also a surveillance
19 program. It's conducted through a
20 company called Inflexxion.

21 Q. Oh, that's the Inflexxion?

22 A. Yes.

23 Q. Okay. And that data was
24 collected, correct?

1 A. Yes.

2 Q. Do you know if that data was
3 in fact used and provided to the payer
4 and physician audience?

5 A. It would have been
6 through -- I'm not sure if it was
7 provided to a payer audience or not. It
8 might have been as part of the data that
9 we had for patients.

10 Q. And you had explained to me
11 the letter, you know, if a physician were
12 to request information about abuse. Were
13 there other ways that a physician or a
14 payer would learn of the results of
15 observational studies using RADARS and
16 Inflexxion data?

17 A. Well, I had published -- I
18 had published a study of 31 months of
19 RADARS for the immediate release. And so
20 if they went online and typed in RADARS,
21 they might have found it that way.

22 Q. Could a sales -- could a
23 sales rep provide that published study to
24 a physician or to a payer?

1 A. No.

2 Q. They'd have to ask for it?

3 A. Yes.

4 Q. Could it be shown in a
5 continuing medical education arena?

6 A. I don't remember whether it
7 was or not. And I don't remember when
8 the rules had changed. We talked about
9 that earlier, about when the company
10 wasn't able to provide that data. So
11 before that I don't want to speculate. I
12 don't know.

13 Q. Okay. "Research partnership
14 with payers, payer tools, et cetera."

15 That would be a partnership
16 with an insurance company or a large
17 managed care organization or something
18 like that with respect to lower abuse
19 potential?

20 A. So that is highlighted in
21 blue. And if you note, the footnote says
22 "HECOR studies" in light blue. So I'm
23 not certain what the outcomes group was
24 planning on doing with that type of

1 information or what the nature of what
2 those studies might look like.

3 Q. Do you have any recollection
4 of whether something like that was done
5 using data from any -- using any payer
6 data?

7 A. I don't recall.

8 Q. Is it your understanding
9 that there is payer data with respect to
10 abuse or misuse or addiction or any --
11 any types of data points with payers?

12 A. I'm not aware of any.

13 Q. Are you familiar with any of
14 the FDA-mandated post-surveillance
15 studies that are being conducted with
16 respect to abuse or addiction currently?

17 A. A little bit. I was
18 involved in some of the early discussions
19 and then I transitioned off and other
20 people at the company took those over.
21 So I'm not current, and I don't know
22 where they had left it.

23 Q. When you were involved, were
24 you familiar at all with what datasets

1 would be used?

2 A. No. I just remember a
3 discussion about which drugs they were
4 considering. But that's -- that's the
5 extent of what I recall.

6 Q. Do you ever -- were you
7 familiar or did you ever hear what
8 patient populations might be used or
9 what, you know -- like a veterans data or
10 Department of Defense data or anything
11 like that, that would be used for those
12 studies?

13 A. I don't recall. As I said,
14 I was on and off in a fairly early stage
15 where a lot of discussion was still
16 going. That was sort of very draft in
17 those days.

18 Q. And then the Nucynta ER and
19 classwide REMS.

20 Do you see that?

21 A. I do.

22 Q. Did you have any involvement
23 in the REMS?

24 A. I had some involvement in

1 the REMS. Some the -- the active
2 surveillance programs that I had
3 developed, those were rolled into the
4 REMS and some of the other activities as
5 well.

6 Q. And what does REMS stand
7 for?

8 A. Risk -- risk evaluation and
9 mitigation strategy.

10 Q. Then the special population
11 and mechanism of action differentiation,
12 that audience would be the physician, and
13 again, you have in light blue, that's an
14 outcomes research proposed study --

15 A. Yes.

16 Q. -- for a prospective
17 registry of patients with cancer pain.

18 Do you see that?

19 A. I do.

20 Q. Any knowledge whether that
21 was done?

22 A. I don't.

23 Q. The mechanism of action
24 differentiation pilot trials, smoking

1 cessation trial, and the testosterone
2 trial, what is your understanding of what
3 those pilot trials were attempting to
4 study?

5 A. I'm not familiar with the
6 smoking cessation trial, per se. For the
7 testosterone trial there is clinical
8 information that patients on prolonged
9 chronic opioid use may have reduced
10 libido. We talked about the proposed
11 dual mechanism, and because of less
12 effect potentially at the opioid
13 receptor, less opioid effect, that
14 hypothesis was that there may be a less
15 effect for patients on their libido if
16 they were using medications such as
17 tapentadol. That was a hypothesis.

18 The other thing I just want
19 to point out as we're talking about this,
20 is on the bottom, that this is a draft.
21 So it's unclear -- we've already
22 indicated that these studies may not have
23 been either initiated or gone on. But
24 these were some of the things that were

1 proposed.

2 Q. The fact that this is a
3 draft, that doesn't change any of the
4 answers that you've given to me?

5 A. No, it doesn't. But whether
6 the studies actually moved forward or
7 not, these were what were being proposed.

8 Q. Okay.

9 A. Yes.

10 Q. Do you know if the
11 testosterone trial went forward?

12 A. Not that I'm aware of.

13 Q. If something like that went
14 forward, do you know if there's any
15 reason why an audience would not be
16 payers as well as physicians?

17 A. No, I don't.

18 Q. Then --

19 A. It says primary audience on
20 the side. So certainly other audiences
21 were possible.

22 Q. Okay. And then the final
23 one is, "Lower real world resource
24 utilization."

1 Do you see that?

2 A. Yes.

3 Q. Do you know what that means?

4 A. Not exactly.

5 Q. Let's see, if we look at the
6 bullets, if it -- if it helps jog your
7 memory. What does MRU mean?

8 A. Medical research
9 utilization.

10 Q. And that's medical research
11 utilization data collected from Phase IV
12 trials?

13 A. Right.

14 Q. Do you see that? And the
15 intended audience would be a payer?

16 A. Yes.

17 Q. And what type of data would
18 assist a payer from Phase IV trials?

19 A. If the patterns from the
20 data would show, for example, how many
21 pills that people actually take a day.
22 For people participating in the study,
23 did they need to take it? For an
24 immediate release, if it's every four to

1 six hours, was the drug being used more
2 at every six hours or every four hours.
3 For -- depending on the medical
4 conditions that they have, how those
5 drugs would be used.

6 In addition it might be,
7 what is the type of care that went along
8 with it. You know, doctor visits, things
9 like that. So that type of data.

10 Utilization within the
11 healthcare system, those are some of the
12 things with medical research utilization.

13 Q. Could that take -- could
14 that -- what was it? Medical -- medical
15 research utilization data, could that
16 tell you how many pills a patient was
17 prescribed, and then you could determine
18 how many they took a day?

19 A. Depending how accurate the
20 pill counts were, whether the people
21 actually recorded the pill counts, and
22 sometimes patients don't always remember
23 what they take. So it's -- the study
24 wasn't designed specifically to address

1 pill counts, per se. They may have been.
2 But the -- the data -- the quality would
3 be -- would depend.

4 Q. So you'd be getting that
5 data from -- from whatever was provided
6 in the Phase IV trials. You'd be --
7 you'd be looking back at those trials to
8 try to determine if you could tell how
9 many pills for example, a patient took a
10 day?

11 A. Right. But keep in mind
12 that the studies would have included
13 exclusion criteria. So people with a
14 history of significant psychiatric
15 disorder, people with a history of drug
16 addiction, would not be usually able to
17 participate in those studies.

18 So if you wanted to have
19 issues on rates of addiction for people
20 who have a history of addiction or some
21 of the medical conditions that would
22 predispose to do addiction, those people
23 would have been usually excluded from the
24 trials to have a very homogenous

1 population. So there -- it might be
2 limited in terms of how much it could
3 inform you on addiction.

4 Q. Is it your understanding
5 that Fishbain and Cochrane did not have
6 those exclusions?

7 A. I'd have to look at those
8 articles and -- to talk more about it.

9 Q. And then the next two have
10 the light blue. "A retrospective data
11 analyses, such as claims, EMR, medical
12 charts, of real world BID dosing and
13 medical resource utilization." That's
14 something that would have been something
15 done by outcomes research?

16 A. Yes.

17 Q. And that would have been,
18 looking back, when it says retrospective
19 data analyses, looking back at any data
20 that existed to try to put together a
21 study or some sort of retrospective
22 study?

23 A. I don't know if I would say
24 any data. They sort of give some

1 examples, I think, of places where they
2 were thinking about going, claims data,
3 EMR, or medical charts, real -- real
4 world dosing.

5 Q. So this would have been
6 potentially looking back at medical
7 charts of individuals who were prescribed
8 opioids for chronic pain?

9 A. Again, that's -- that's what
10 it looks like. I don't know.

11 Q. And would it be fair to say
12 that a payer may, in fact, have those
13 medical charts, correct?

14 A. It depends on the payer. It
15 depends on the type of information they
16 collect. They may have it, but it may be
17 very limited just to their own system.
18 They may be interested in hearing what's
19 happening in other groups to make the
20 data more generalizable.

21 Q. And then studies examining
22 patient, healthcare providers,
23 satisfaction and preference. Would those
24 be surveys that would be taken?

1 A. Presumably.

2 Q. If you look on Page 5,
3 building evidence for lower abuse
4 potential. And that would be of Nucynta,
5 correct?

6 It would be for Nucynta,
7 correct?

8 A. Yeah, I'm looking at the
9 slide.

10 Q. Okay.

11 A. Yes.

12 Q. And the mechanism of action
13 here, that would provide the reason to
14 believe that lower abuse potential was a
15 possibility, correct?

16 A. This was the hypothesis that
17 would be used, yes.

18 Q. What's the purpose of a --
19 of a slide like this with the cogs in the
20 wheel here?

21 A. I didn't prepare the slide,
22 so I'm not exactly sure. I think what
23 they are trying to show is that in order
24 to put the evidence together, that the

1 evidence would need to be starting off
2 with a hypothesis and to try and see how
3 plausible it would be, one would need to
4 conduct rigorous studies confirming the
5 low abuse potential. Some of those would
6 be studies as set forth by the FDA that
7 would need to be done.

8 Coupled with actual data
9 from -- from people who have been treated
10 with the medication. And as the slide
11 indicates, data on addiction and other
12 information about it as well, including
13 overdose, deaths and other information
14 that would be acquired from the
15 community.

16 Q. Would that be actual data on
17 addiction, overdose and deaths of
18 individuals on the drug?

19 A. Presumably, or it may be on
20 other medications for comparative. Those
21 data can be complicated though, because
22 for overdose, sometimes patients are on a
23 number of different substances leading to
24 the overdose.

1 But the person who created
2 this slide felt that they were going to
3 use a combination of rigorous clinical
4 studies as well as actual data on people.

5 Q. Were the rigorous clinical
6 studies ever done?

7 A. Not to the best of my
8 knowledge. There are other studies that
9 were done, rigorous studies, for the
10 extended-release formulation, showing
11 that it is very difficult to break into
12 the extended-release protective
13 mechanisms, but -- certainly those were
14 rigorous, but again some of the -- I'm
15 not sure what other studies they are
16 talking about. So I -- I don't know
17 whether -- I am not aware of other
18 studies being done.

19 Q. So you don't know if there
20 were rigorous studies done with respect
21 for example, concerning likability?

22 A. We did a likability study
23 early on looking at it. But there may
24 have been studies, rigorous studies later

1 on in 2012. There was -- those were some
2 studies, data from that likability study,
3 abuse potential study. I'm not sure, it
4 says interim in 2014. I don't know when
5 that study -- I don't have information
6 from that study to inform us today.

7 Q. Okay. Do you know what in
8 red here on the actual data on addiction,
9 it says, "Not enough data until 2015 or
10 later"?

11 Do you know why that is?

12 A. I don't.

13 Q. You can put that away.

14 MS. CONROY: We'll mark as
15 Exhibit 7, JAN-MS-02119672 through
16 9687.

17 (Document marked for
18 identification as Exhibit
19 Janssen-Vorsanger-7.)

20 BY MS. CONROY:

21 Q. This is -- Exhibit 7 is an
22 e-mail dated September 16 of 2003, to you
23 from Mo Sacoer. Who is Mo Sacoer?

24 A. Mo Sacoer is someone who

1 worked with Dr. Nathaniel Katz to put
2 together our 2003 abuse advisory board.

3 Q. Abuse advisory board?
4 That's the Ad Board?

5 A. Yes.

6 Q. Okay. So it would be opioid
7 abuse advisory board.

8 Is Mo Sacoer a -- a medical
9 doctor?

10 A. He is a medical doctor by
11 training, but he runs a company that puts
12 together advisory boards.

13 Q. Okay.

14 A. Or did at that time.

15 Q. And Nat Paul Katz. That's
16 Dr. Katz who you've published with?

17 A. Yes, that's correct. From
18 Dartmouth, Massachusetts.

19 Q. And in 2003 was he a key
20 opinion leader for Janssen?

21 A. I believe so.

22 Q. Would he have been paid as a
23 key opinion leader or have a consultancy
24 agreement whereby he was paid?

1 A. He would have had a
2 consultancy agreement as part of these
3 activities.

4 Q. Who is ACohen@MMS-USINC.com?

5 A. I don't know.

6 Q. And it looks like, if you
7 turn the page, the Sacoor Medical Group,
8 international pharmaceutical industry
9 consultants, Chairman Dr. Sacoor, drafted
10 a roadmap for the advisory board
11 prescription opioid abuse in chronic
12 pain.

13 Do you see that?

14 A. Yes.

15 Q. And he says, "This document
16 has been prepared on the basis of a
17 detailed telephone briefing by Dr. Gary
18 Vorsanger and my subsequent detailed
19 discussion with Dr. Nat Katz."

20 Do you see that?

21 A. Yes.

22 Q. And any reason to doubt
23 that?

24 A. No.

1 Q. "It's intended to convey my
2 understanding of the background as well
3 as the Ad Board objectives and to outline
4 the approach recommended as discussed and
5 agreed with Dr. Katz as being the most
6 appropriate in fulfilling Janssen's
7 goals."

8 Do you see that?

9 A. Yes.

10 Q. Is that what Dr. Sacoer's
11 assignment would have been back in 2003,
12 late summer, early September?

13 A. Yes.

14 Q. And if you take a look on
15 Page 4 of 13. And you're free to look.
16 There's a -- there's a -- the roadmap has
17 a table of contents, and then action
18 steps, timetables, and roles.

19 Do you see that?

20 And it says, "Janssen are
21 launching a new product which will follow
22 on the heels of Duragesic's"?

23 A. I'm sorry. Action steps,
24 timetables, yes, okay.

1 Q. Okay. "Janssen are
2 launching a new product which will follow
3 on the heels of Duragesic."

4 Do you see that in the first
5 sentence?

6 A. Yes.

7 Q. Which product is that?

8 A. Janssen was considering a
9 second product that would be similar to
10 Duragesic, but have a medication -- an
11 opioid antagonist that would be a part of
12 this new system.

13 Q. And it was part of a patch
14 system?

15 A. It would have been a patch.

16 Q. Okay. And it would have
17 been different. It would have been --
18 would you have termed it a reservoir
19 patch or a matrix patch, what would you
20 call it?

21 A. I don't remember. I think
22 it was a matrix patch with this. But I
23 don't recall.

24 Q. Okay. And it was expected

1 that the new product would have lower
2 abuse potential. Is that -- is that fair
3 to say, or that was the hope?

4 A. We wanted to make sure that
5 that would be the case.

6 Q. Okay. At this time you did
7 not know if that would be the case,
8 correct?

9 A. Right. We thought that it
10 would be, we wanted to have
11 well-controlled studies to begin to
12 address that question.

13 Q. It says, if you look further
14 in the middle of the page, "Janssen would
15 like to come up with several studies
16 that, taken as a package with the drug
17 liking study, would convince clinicians
18 that it does have a product with lower
19 abuse potential. The dilemma is that
20 there really is not a lot of good
21 methodology that is widely accepted for
22 the studies that need to be done."

23 Do you agree with that?

24 A. Yes.

1 Q. "The studies we're talking
2 about" -- and I'm reading, going on
3 here -- "will not be a part of the new
4 drug application submission package."

5 Do you see that?

6 A. Mm-hmm.

7 Q. So these studies would not
8 be something that would be going to the
9 NDA as part of the approval process,
10 correct?

11 A. That's what it says.

12 Q. But -- I'm sorry. "However,
13 the quality and rigor of the science
14 needs to be something that Janssen can
15 put in front of the FDA or any other
16 regulatory body at some point in time."

17 Do you see that?

18 A. Yes.

19 Q. Have you seen this document
20 recently?

21 A. No, I have not.

22 Q. If you go to Page 6, under B
23 at the bottom of the page, there is a
24 header that says, "Clinical trial to

1 assess the rates of addiction in patients
2 being prescribed various opioids."

3 Do you see that?

4 A. Yes.

5 Q. And then it says, "A key
6 problem here is that nobody really knows
7 how to define addiction."

8 Do you see that?

9 A. Yes.

10 Q. And is that something that
11 you discussed with Dr. Sacoor and
12 Dr. Katz?

13 A. Yes.

14 Q. And why wasn't there a
15 definition of addiction at this time?

16 A. I think there was -- there
17 was definitions of addiction, but not a
18 definition that everybody could agree on.

19 Q. Did individuals at Janssen
20 agree on a definition?

21 Or let me ask it this way.

22 Who is it that didn't agree
23 on the definition?

24 A. I don't know how to answer

1 that question. I don't know what
2 different people thought about it in
3 terms of the definition of addiction.

4 Q. How did you know that there
5 was -- that there was an issue with the
6 definition of addiction?

7 A. Because this meeting was
8 convened with key experts. Dr. Nathaniel
9 Katz is an expert in this area, and it
10 was generally acknowledge that there's
11 not a -- there's not a good definition of
12 addiction.

13 We also talked about the
14 ACTION group in that publication that
15 came out in 2013 a decade later. And
16 even at that point there was still not a
17 good agreement on experts on the
18 definition of addiction.

19 Q. And that would make it
20 difficult to determine the abuse
21 potential, correct?

22 A. No. It would be difficult
23 to define and measure addiction in a
24 clinical trial when we're unable to get a

1 specific agreement among people on what
2 addiction would be, unless we can come up
3 with a definition that people were
4 willing to accept for purposes of the
5 discussion. But Dr. Sacoer identified
6 the challenge here.

7 Q. You were comfortable with
8 Dr. Fishbain's and the Cochrane analyses'
9 definition of addiction, at least as of
10 whenever those studies came out in 2010
11 to 2013?

12 A. I was comfortable with the
13 discussion that they put in.

14 Q. And was there general
15 acceptance of their definition of
16 addiction?

17 A. The articles that I
18 referenced earlier were considerably
19 later than when this advisory board took
20 place.

21 Q. I was referencing when you
22 said as of 2013 it was still an issue.

23 A. It was -- yes. And it was
24 still under discussion.

1 Q. Okay. So the Cochrane and
2 Fishbain didn't solve the problem?

3 A. I think the quality of the
4 evidence from the information that they
5 included on it were compelling for me.

6 Q. Did they have a compelling
7 definition of addiction for you?

8 A. Yes.

9 Q. And do you know if their
10 definition has been widely accepted or
11 are there still issues with the
12 definition of addiction?

13 A. I don't know.

14 Q. You'll see that there's a
15 discussion on Page 6 going into Page 7
16 about what such study would potentially
17 look for and what kind of data would be
18 collected. And then there would be an
19 adjudication process where an addiction
20 psychiatrist would sit in a room with a
21 pain management physician and would
22 receive information from all these
23 sources on all the patients that met a
24 certain threshold criteria. They would

1 receive information from all these data
2 sources, put it all together, and decide
3 if this patient is addicted definitely,
4 probably, possibly, or not.

5 Do you see that?

6 A. Yes.

7 Q. And then it says, "It would
8 be just like adjudicating upper GI bleeds
9 or adjudicating thrombotic events or
10 whatever in clinical trials. So there's
11 ample precedent for this approach. This
12 would also be a ground-breaking
13 approach."

14 Do you see that?

15 A. Yes.

16 Q. So Janssen at this time was
17 looking into the ability to conduct one
18 or more clinical trials that would
19 attempt to quantify addiction in chronic
20 pain patients, correct?

21 A. We were looking -- yes.

22 Q. And then he says, "Clearly
23 one would need several thousand patients
24 requiring 30 to 40 centers."

1 Do you see that?

2 A. Yes.

3 Q. Any reason to disagree with
4 that?

5 A. No.

6 Q. How many patients do you
7 believe were on opioids for chronic pain
8 or were prescribed opioids for chronic
9 pain in 2003? Do you have a ballpark?

10 A. I don't.

11 Q. So we don't know -- as you
12 sit here today, you can't determine what
13 percentage several thousand patients
14 would be of the universe of patients on
15 chronic pain therapy, opioid chronic pain
16 therapy?

17 A. To have individuals to fit
18 the criteria, this was an estimate they
19 had. And then based on the number of
20 centers that would be available -- would
21 have the appropriate number of patients.

22 Q. Okay. Then it says,
23 "Janssen's (currently in planning)
24 several thousand patient studies could

1 potentially be the infrastructure
2 investigation for this type of trial.
3 However, for the purpose of our meeting
4 we certainly don't need to identify all
5 40 of these clinical trialists."

6 Do you see that?

7 A. Yes.

8 Q. So apparently Janssen
9 already had a several thousand patient
10 study that at least they were planning
11 that could potentially be used or that
12 you could add an endpoint of addiction
13 to. Is that what that means?

14 A. I don't know -- I don't know
15 what this -- I don't know what they're
16 referring to at this point.

17 Q. Well, aside from -- what
18 you're saying is you don't know what --
19 what study was currently -- what several
20 thousand patient study was currently in
21 planning in 2003?

22 A. Yes.

23 Q. Without knowing what it was,
24 do you have any reason to doubt that

1 there was a several thousand patient
2 study that was in planning at Janssen at
3 that time?

4 A. I simply don't know.

5 Q. Well, would Dr. Sacoer have
6 made that up?

7 A. Currently in planning may
8 have meant we were thinking about it. It
9 doesn't mean anything more than that.

10 Q. Correct. I think that's
11 what he says. It's currently in
12 planning.

13 But would the idea here to
14 have added the addiction endpoint to
15 whatever several thousand patients study
16 was in planning, regardless of the state
17 of the planning?

18 A. I'm sorry. I'm not sure
19 what you're getting at with this.

20 Q. Where it says, "Several
21 thousand patient study could potentially
22 be the infrastructure investigation for
23 this type of trial," what that means is
24 the patients that were being used

1 potentially in this -- currently in the
2 planning stage study at Janssen in 2003,
3 could be the same patient population for
4 this addiction study?

5 A. No, I understand that. I'm
6 just not aware there was a several
7 thousand patient study in 2003 that could
8 have been used for this purpose. That's
9 why I'm saying I don't completely
10 understand what he's saying. We may -- I
11 don't want to speculate on what might
12 have been.

13 Q. Well, I think he is
14 speculating here. He's saying it might
15 have been that there was such a study.

16 Do you have any reason to
17 doubt that there was such a study in
18 Dr. Sacoer's, Dr. Katz's, and in your
19 mind at this time?

20 A. I'm not sure that there was
21 a --

22 MR. LIFLAND: Object to the
23 form of the question.

24 THE WITNESS: I don't recall

1 a study that he would have been
2 talking about, that they could
3 have piggy-backed off to use this
4 information. I don't recall.

5 BY MS. CONROY:

6 Q. If you go to Page 8, it's
7 the very next page. There's also the
8 evaluation of diagnostic criteria. And
9 this would be a study to evaluate
10 diagnostic criteria for addiction in the
11 setting of chronic pain treatment with
12 opioids. Do you see that?

13 A. Yes.

14 Q. Do you know if any such
15 study has ever been done to develop
16 diagnostic criteria for addiction in the
17 setting of chronic pain treated with
18 opioids to date?

19 A. I'm not aware of it at this
20 point.

21 Q. Do you know, to date, if any
22 study similar to what is stated here in
23 Section B, "A clinical trial to assess
24 the rates of addiction in patients being

1 prescribed various opioids," has ever
2 been conducted by Janssen or Johnson &
3 Johnson? Page 6.

4 A. Not that I'm aware of.

5 Q. You can put that away.

6 Let me give you a few of
7 these at once because they relate to one
8 another.

9 (Document marked for
10 identification as Exhibit
11 Janssen-Vorsanger-8.)

12 BY MS. CONROY:

13 Q. I'm going to mark as
14 Exhibit 8 is what appears to be the --
15 I'll let you define it. But I think it's
16 more or less the agenda of the Ad Board
17 meeting on November 3rd and 4th. And
18 that is JAN-MS-02113207 through 219.

19 MS. CONROY: And Exhibit 9
20 which is a January 27, 2004,
21 summary of the abuse advisory
22 board. And that is
23 JAN-MS-02105452 through 628.

24 (Document marked for

1 identification as Exhibit

2 Janssen-Vorsanger-9.)

3 BY MS. CONROY:

4 Q. So first of all, we have the
5 draft program. And this is from Clare
6 Harte. Who is she, do you remember?

7 A. Clare Harte -- yes. Clare
8 Harte was a project manager who worked
9 with me.

10 Q. Okay. And this was to Jim
11 Eckhardt, did he work -- was he a
12 coworker?

13 A. Jim -- Jim Eckhardt is --
14 worked -- worked at Janssen.

15 Q. Medical affairs?

16 A. He was in marketing.

17 Q. Marketing?

18 A. Mm-hmm.

19 Q. Okay. Clare Harte was in
20 your department?

21 A. Yes.

22 Q. Barry Pritchard?

23 A. Also in marketing.

24 Q. Rick Blockinger?

1 A. I believe also in marketing.

2 Q. And then to you as well?

3 A. Yes.

4 Q. And Clare says, "Here is the
5 final draft of the program. Any
6 immediate comments are welcome. An
7 official invite will be coming from Mo
8 Sacoor later this week."

9 It looks like Clare, a
10 little bit earlier in the day, had
11 cleaned up and spaced the agenda out a
12 bit for Dr. Sacoor. Do you see that?

13 A. Yes.

14 Q. Do you recall attending this
15 Ad Board meeting?

16 A. Yes.

17 Q. In November of 2003?

18 A. Yes.

19 Q. Is this the -- who was
20 running this? Were you -- were you the
21 host or was --

22 A. I was. This was a
23 Janssen-sponsored Ad Board. I was the
24 host working with Dr. Sacoor and

1 Dr. Katz.

2 Q. And had you hosted an Ad
3 Board prior to this date for Janssen?

4 A. Probably, yes.

5 Q. This is a key opinion leader
6 advisory board. Would the individuals
7 who were in attendance from outside of
8 Janssen, would they either be paid for
9 their time to attend this or be under
10 some sort of a consulting agreement with
11 Janssen?

12 A. They would have been under a
13 consulting agreement.

14 Q. Every one of them?

15 A. Yes.

16 Q. If you take a look at
17 Page 4, at the 9:10 a.m. program, which
18 is called Icebreaker Number 2.

19 "Shortcomings in evidentiary base
20 relating to addiction in the setting of
21 prescription opioid therapy for chronic
22 pain."

23 And the questions that are
24 here are the bullet points. "Are opioids

1 addictive when prescribed for chronic
2 pain?"

3 Was that a topic that you
4 acknowledged should be discussed among
5 the key opinion leaders?

6 A. The icebreaker is more a way
7 of people introducing themselves as to
8 their interests. And Dr. Passik thought
9 this would be something of interest to
10 the group.

11 Q. And is it your best memory
12 that it was of interest to the group?

13 A. Yes.

14 Q. I'm sorry?

15 A. Yes, it was.

16 Q. And the -- then he asks,
17 "Have any previous studies addressed this
18 issue effectively?" And that there's
19 historical confusion between prevalence
20 and incidence. How to measure incidence
21 of addiction in clinical trials. And the
22 implications and guidance for Janssen
23 clinical trials for its new opioid
24 analgesic.

1 Do you see that?

2 A. Yes.

3 Q. Those were approved topics.
4 You -- you approved his discussion of
5 these topics, correct?

6 A. Yes.

7 Q. And who is Steven Passik?

8 A. Dr. Passik is a pain
9 specialist, pain expert. He has a
10 background in addiction medicine. He
11 is -- as well, he's a psychologist.

12 Q. And how did you know him?

13 A. He was one of -- one of
14 the -- one of the Janssen key opinion
15 leaders.

16 Q. Did you know him before you
17 went to Janssen?

18 A. No.

19 Q. Are you in any contact with
20 Dr. Passik today or as of 2015?

21 A. Not directly as it relates
22 to this. Dr. Passik was in a new role in
23 a -- in a company, and he and I
24 communicated briefly about that.

1 Q. What -- what new company is
2 he in?

3 A. I forget the name of the
4 company now.

5 Q. What's his area?

6 A. In pain management.

7 Q. Pain management. Does he
8 have anything to do with addiction
9 therapy?

10 A. I don't know what he's doing
11 currently today.

12 Q. He is not a medical doctor?

13 A. I believe he is a Ph.D.

14 Q. Do you know if he was a key
15 opinion leader for any company other than
16 Janssen at the time?

17 A. I wouldn't have that
18 information.

19 Q. Would you have known it at
20 the time for example, if he was also a
21 key opinion leader for Purdue Pharma?

22 A. Not necessarily, no.

23 Q. If you go to Page 6.

24 Icebreaker Number 5 at 10:00 a.m. "The

1 terminology/semantics of prescription
2 opioid abuse."

3 And this is Dr. Jim Zacny.
4 Do you see that?

5 A. Yes.

6 Q. Do you know him?

7 A. I met him around the Ad
8 Board activities and I knew of him.

9 Q. And what was his specialty,
10 do you know?

11 A. I don't recall now.

12 Q. Okay. Would you have known
13 at the time?

14 A. Yes.

15 Q. And he is going to talk
16 about addictionists versus pain
17 specialists versus scientists versus
18 ASAM. What does that mean, ASAM?

19 A. I'm not certain.

20 Q. Okay. DSM-IV is the
21 diagnostic manual, correct?

22 A. Yes.

23 Q. And that provides a
24 definition of -- of dependence or

1 substance abuse, that sort of thing?

2 A. Yes.

3 Q. Is ASAM a similar type of
4 diagnostic or method of diagnosing
5 addiction?

6 A. I don't know what ASAM
7 stands for in this context.

8 Q. We might see it further on.
9 I think I've seen the acronym elsewhere.
10 He says, "Can we establish
11 an acceptable common vocabulary for our
12 Ad Board?"

13 And then he says, "What are
14 the implications for Janssen's future
15 clinical trials, in terms of how the
16 outcomes that we're interested in should
17 be defined? DSM-IV, the most widely used
18 and validated diagnostic criteria, still
19 refers to 'substance dependence
20 disorder,' which has been shown
21 convincingly to be completely irrelevant
22 to the chronic pain patient.

23 Do you see that?

24 A. Yes.

1 Q. Was that your understanding
2 at the time, that DSM-IV was irrelevant
3 to the chronic pain patient?

4 A. I didn't have an opinion on
5 the matter.

6 Q. Okay. Take a look at the
7 11:00 a.m. Icebreaker Number 8, on Page
8 7. Outcome measures in clinical trials
9 relevant to addiction to opioids in
10 chronic pain patients. That's by --
11 being given by Bruce Rounsaville, M.D.
12 Who is that?

13 A. I don't recall who this
14 individual is.

15 Q. He would have been a KOL for
16 Janssen, right?

17 A. He would have been someone
18 who we invited to this advisory board
19 based on his background.

20 Q. And when he says, "Which
21 diagnostic criteria should be used in the
22 chronic pain population?" what he's
23 talking about is what's the best way to
24 tell if a patient is addicted to opioid

1 pain medication, correct?

2 A. That's what it would appear.

3 Q. Then on Page 13, you gave
4 the -- you gave the wrap-up, and you
5 closed the advisory board after there
6 were open discussion on Tuesday,
7 November 4th, correct?

8 A. Yes.

9 Q. Okay. Let's take a look at
10 Exhibit 9 that I've passed to you, right
11 there. Did you prepare your own notes at
12 this meeting, do you know?

13 A. I'm not sure what you're
14 asking me.

15 Q. Did you prepare your own
16 notes of what the speakers were saying
17 and discussing at the November 3rd and
18 4th, 2003, Ad Board meeting?

19 A. So part of the contract with
20 Dr. Sacoer was that people from either
21 his company or he may have hired medical
22 writers, I don't remember now, to record
23 the information.

24 Q. So you wouldn't -- you

1 did -- you could listen. You didn't need
2 to take notes. You knew someone would be
3 taking notes.

4 A. That's correct. Yes.

5 Q. And if you take a look at
6 this document, Exhibit 9, which is
7 JAN-MS-02105452 through 628, does this
8 appear to you to be the notes that
9 Dr. Sacoer said his group would take care
10 of?

11 And I'll say that the front
12 page is an e-mail dated January 27, 2004,
13 from you to Dr. Katz. The subject line
14 is "Summary of abuse advisory board."
15 And then you say to Nat Katz, "Here is a
16 copy of the summary produced by Mo."

17 Do you see that?

18 A. Yes.

19 Q. So is that what you were
20 talking about? These -- this would have
21 been the notes that were taken by
22 Dr. Sacoer at the meeting?

23 A. I'd have to take a look at
24 the document to confirm.

1 Q. Take -- yeah, take a look.

2 A. This appears to be the
3 summary describing the people who
4 attended and some of the other content as
5 well.

6 Q. Would they be some other
7 summary?

8 A. No. This looks -- appears
9 to be the summary.

10 Q. Okay. And I see it's the
11 attachment with the summary. The summary
12 is called "Final to Janssen." So as best
13 you can tell, this is the final summary
14 of that meeting provided by Dr. Sacoer?

15 A. Correct. I don't know if
16 it's complete. But as best I can tell,
17 this is what it looks like.

18 Q. Okay. Take a look at Page 1
19 of 171 which is Bates 458.

20 It lists the Ad Board
21 objectives. The main goals were, "To
22 discuss and develop a package of clinical
23 and other research studies/trials
24 designed to:

1 "Inform us about the
2 relative abuse liability potential of the
3 next generation of MRO" --

4 moderate-release opioids? Is that what
5 that is?

6 A. I'm not sure what the M
7 stands for.

8 Q. Okay. Or maybe
9 modified-release opioids?

10 A. Modified-release opioids.

11 Q. Duragesic was a
12 modified-release opioid?

13 A. I don't remember. I don't
14 remember how this term was used.
15 Certainly Duragesic is an
16 extended-release.

17 Q. So that means that the
18 release would be modified in some -- in
19 some way, correct?

20 A. Controlled -- released,
21 yeah. But I -- this is not a term that
22 I -- that jumps -- that I recall at this
23 moment.

24 Q. Okay. "Inform us about the

1 relative abuse liability potential of the
2 next generation MRO analgesics for the
3 treatment of chronic pain."

4 A. Mm-hmm.

5 Q. "Be persuasive to clinicians
6 and regulators of the lower abuse
7 potential of the new generation of MRO
8 analgesics for chronic pain.

9 "Secondly, select from the
10 above-mentioned package the four to five
11 key must-have studies, which to flesh out
12 in more detail, with more specific study
13 parameters relating to study design,
14 timelines and costs."

15 Do you see that?

16 A. Yes.

17 Q. Is that your memory of the
18 objectives?

19 A. Yes.

20 Q. If you could turn to Page 16
21 of 171. Actually, Page 15 will make it a
22 little bit easier.

23 The document has sort of a
24 historic overview of the use of opioids

1 through the years. And Phase II was the
2 early '80s and through the '90s, there in
3 the center of the page. And, "Begin a
4 discussion of opioids for the management
5 of moderate to severe pain associated
6 with cancer, AIDS, and other advanced
7 medical illnesses."

8 Do you see that?

9 A. Yeah.

10 Q. And it says, "At the same
11 time there was a very gradual movement to
12 think about the use of opioids for
13 chronic nonmalignant pain."

14 Do you see that?

15 A. Yes.

16 Q. Is that your understanding
17 that it happened in the early '80s
18 through the early '90s?

19 A. My understanding was more
20 late '80s than the '90s, but...

21 Q. Okay. And then it says,
22 "And this culminated in an important
23 watershed event which was the publication
24 of a consensus document jointly by the

1 American Pain Society and the American
2 Academy of Pain Medicine that essentially
3 said there is a subpopulation of patients
4 with chronic pain who should be treated
5 with opioids because they act like the
6 usual cancer patient. They gain
7 sustained benefits without the loss of
8 efficacy due to tolerance or any other
9 factor. Their side effects are tolerable
10 in a way that would be safe and
11 effective."

12 Do you see that?

13 A. Yes.

14 Q. And that was the -- that was
15 the understanding of the group, including
16 Janssen, on November 3rd and fourth in
17 2003, correct?

18 MR. LIFLAND: Object to the
19 form of the question.

20 THE WITNESS: I don't
21 understand the question.

22 BY MS. CONROY:

23 Q. Was this Dr. Sacoer's
24 understanding?

1 A. This was a summary of the
2 impressions of the people -- the key
3 opinion leaders who participated at the
4 meeting.

5 Q. And does it also include the
6 opinions of, for example, yourself or
7 Dr. Sacoor?

8 MR. LIFLAND: Object to the
9 form of the question.

10 THE WITNESS: I don't know
11 what Dr. Sacoor's opinion was. I
12 think this summarized what
13 Dr. Sacoor had and the people
14 working with him had heard from
15 the key opinion leaders
16 participating at the meeting.

17 BY MS. CONROY:

18 Q. Okay. Do you -- do you
19 agree that the consensus document was a
20 watershed moment?

21 A. I don't have an opinion at
22 this point.

23 Q. Okay. If you take a look
24 further. It says, "Abuse and addiction

1 as a potential, mentioned and were
2 already inhibiting them from going
3 forward so they had to get past it. And
4 the oxycodone problem has led to a
5 wake-up call."

6 Do you see that?

7 A. Yes.

8 Q. What was the Oxycodone
9 problem in 2003, if you know?

10 A. I'm assuming what this is is
11 there were more mentions of abuse of
12 oxycodone, that they are beginning to see
13 this or had seen this before.

14 Q. Okay. It goes on. "At a
15 national level the goal is to continue to
16 identify those patients who would be
17 appropriate candidates for long-acting
18 opioid therapy and at the same time
19 recognize the need to have controls so
20 that abuse and diversion are minimized."

21 Do you see that?

22 A. Yes.

23 Q. You agree with that,
24 correct?

1 A. Yes.

2 Q. That -- that was true in
3 2003 and it's true today, correct?

4 A. Yes.

5 Q. "At an individual level,
6 what this means is that every patient who
7 is being considered a candidate for these
8 drugs has to undergo a risk assessment by
9 the clinician and an appropriate element
10 of the prescribing has to be risk
11 management."

12 Do you see that?

13 A. Yes.

14 Q. And that means managing the
15 risk of providing an opioid to an
16 individual patient, correct?

17 A. Yes.

18 Q. And that risk would include
19 that the patient might become addicted to
20 the opioid? Is that one of the risks?

21 A. Yes.

22 Q. They might abuse the opioid
23 or misuse it?

24 A. Yes.

1 Q. Is that one of the risks?

2 A. Yes.

3 Q. Or it might be diverted?

4 A. Yes.

5 Q. And then it says, "So that
6 brings us to the next level, which is
7 what's going to happen now at the level
8 of the individual prescriber?

9 "The use of opioids is going
10 to continue to grow in primary care and
11 that is going to be contingent, of
12 course, on the facilitatory environment
13 on the part of the government and law
14 enforcement."

15 What does that mean,
16 facilitatory environment?

17 A. I don't know what it means.

18 Q. Okay, "driven by studies
19 most of which are going to be funded by
20 industry."

21 That means the studies would
22 be funded by the pharmaceutical industry,
23 correct?

24 A. That -- that was the

1 impression of the people attending the
2 meeting.

3 Q. And yours as well?

4 A. I don't know. Government
5 have a role as well.

6 Q. "What the studies will show
7 hopefully is that there's an element of
8 safety and a manageable level of risk of
9 abuse that can be dealt with so
10 clinicians feel comfortable in selecting
11 patients for this therapy and then using
12 it over time."

13 Do you agree with that?

14 A. Yes.

15 Q. And in part, part of this Ad
16 Board was to come up with studies that
17 would allow clinicians and payers to
18 recognize a manageable level of risk
19 abuse that could be dealt with so that
20 they could feel comfortable selecting
21 patients for therapy and using it for
22 long-term care.

23 A. Provided that the -- that
24 the clinicians continue to monitor the

1 patients so that when the medications
2 were prescribed, they saw the patients
3 regularly and monitored them on an
4 ongoing basis.

5 Q. And why would that be
6 important, to monitor the patients on an
7 ongoing basis?

8 A. To look for the signs that
9 you already discussed, for adverse -- all
10 adverse events, including the ones that
11 you mentioned.

12 Q. And if a physician sees
13 those signs, what should they do?

14 A. They would manage the
15 patient appropriately.

16 Q. What would that mean?

17 A. It would depend on the
18 patient, it would depend on the
19 situation. There's no generalization.
20 They would be -- they would have to be
21 monitoring those like other adverse
22 events.

23 Q. What would be some of the
24 options once a physician identified signs

1 of abuse or adverse events?

2 A. They would have a
3 conversation with the patient about it.
4 Identify what the issues would be.
5 Sometimes patients would need to be
6 switched to other medications if they
7 were able to do so, to avoid that. They
8 would sit and counsel -- certainly
9 education's a key role to explain to
10 patients the importance of using the
11 medications as prescribed and not abusing
12 those. If there was signs of addiction,
13 then they would treat that. They may
14 refer patients to get additional
15 psychological, psychiatric support for
16 their -- for the addiction, et cetera.

17 Q. Would -- at that point would
18 a physician diagnose abuse or addiction?

19 A. I'm not understanding your
20 question.

21 Q. If the physician saw signs
22 of an adverse event related to abuse or
23 addiction, would the physician need to
24 diagnose abuse or addiction in the

1 patient in order to continue to deal with
2 those issues, for example to get
3 psychological support?

4 A. You mean -- I'm still not
5 understanding your question. I'm sorry.

6 Are you saying that they
7 need to have a diagnosis to be able to do
8 that?

9 Q. Sure.

10 A. Well, it -- that would be
11 part of their clinical impression of the
12 patients, to be able to do that.

13 Q. Okay. Go to Page 20. And
14 this is the discussion of Dr. Passik's
15 icebreaker. He talks about minimally
16 monitored drug-only pain therapy. Do you
17 know what that is?

18 A. I don't.

19 Q. If you look on Page 21.

20 Dr. Passik goes on. He says, "There are
21 multiple etiologies of those behaviors.
22 That is the problem we have in the pain
23 management setting. We see a lot of
24 noncompliance, potentially aberrant

1 behavior. But how do we sort out which
2 ones are related to addiction and abuse
3 and which ones are related to inadequate
4 analgesia?"

5 That's what you were talking
6 to me about before, inadequate pain
7 control, correct?

8 A. Yes.

9 Q. And do you agree that those
10 were the issues that needed to be sorted
11 out?

12 A. For -- yes, for patients who
13 were presenting requesting more pain
14 medication, that these are some of the
15 issues that need to be addressed.

16 Q. And then if you turn the
17 page. Dr. Passik goes on to talk about
18 some of the aberrant behavior. But he
19 says, "We don't even know how common any
20 of these various ones are."

21 Do you see that?

22 A. No, I don't.

23 Q. Right in the -- right here
24 in the middle. "So we see the whole

1 spectrum" -- "spectrum. We don't even
2 know how common any of these various ones
3 are."

4 A. Right. That's a comment
5 based on 2003.

6 Q. Do we know how common they
7 are today?

8 A. I don't know.

9 Q. Do you know if anyone knows?

10 A. I don't know.

11 Q. What about in 2015, did you
12 know how common they were?

13 A. I would have to consult the
14 literature to see. I don't have that off
15 the top -- top of my head.

16 Q. Did Janssen ever conduct any
17 studies to determine how common they
18 were?

19 A. How common?

20 Q. The issues that Dr. Passik
21 is talking about, abuse, misuse, aberrant
22 behavior. If you look at the page
23 earlier, he explains a few of them. Do
24 you know if --

1 A. Not to the best of my
2 knowledge.

3 Q. Janssen has not studied
4 this?

5 A. Not to the best of my
6 knowledge.

7 Q. But if we look at page --
8 you may need to look at the bottom of
9 Page 22. He says something very
10 interesting. "Cancer patients are
11 shifted towards lack of aberrant
12 behaviors. Addicts with AIDS who have
13 pain are shifted towards aberrant
14 behavior. And 6 to 10 percent of cancer
15 patients have some vulnerability to
16 addiction."

17 Do you see that?

18 A. Yes.

19 Q. Do you know the basis for
20 that percentage?

21 A. I do not.

22 Q. Then he says, "Same with
23 chronic pain patients. Small subset,
24 somewhere between 6 and 10 percent are

1 having a lot of aberrant behavior."

2 A. Excuse me.

3 Q. Do you know where that
4 percentage comes from?

5 A. I do not.

6 Q. Do you think you knew at the
7 time?

8 A. No.

9 Q. Would you have asked?

10 A. This -- we were gaining
11 information from our key opinion leaders.
12 So this was something we were collecting
13 on it. But we did not -- I did not
14 pursue that with him.

15 Q. Is it possible that this is
16 one of the studies that was available to
17 support the label that iatrogenic
18 addiction is relatively rare?

19 A. I can't comment on that. I
20 don't know.

21 Q. Then there's a discussion of
22 pseudoaddiction. And do you know if
23 there has ever been any study to
24 determine whether or not pseudoaddiction

1 occurs?

2 A. I believe I addressed that
3 earlier. I was not aware of such a
4 study.

5 Q. Okay. Look at Page 25. And
6 if you look at the top -- you may need to
7 look at Page 24 for a little more
8 context. Dr. Passik says, "So the issue
9 is very hard to figure out in the
10 clinical setting, but we see it everyday.
11 And it's not an empirically validated
12 notion particularly. The original paper
13 from 1989 had only 28 cancer cases, when
14 Wiseman and Haddox first wrote the paper.
15 However, frequency of aberrant behavior
16 in chronic opioid therapy patients over a
17 six-month period, 45 percent of the
18 sample had aberrant behavior."

19 Do you see that?

20 A. Yes.

21 Q. Are you familiar with that
22 work?

23 A. I am not.

24 Q. Do you know who Dr. Wiseman

1 is?

2 A. I do not.

3 Q. Is Haddox H-A-D-D-O-X, or do
4 you know another Haddox with the C-K-S?

5 A. This may have been spelled
6 incorrectly.

7 Q. Did you do any follow-up to
8 determine the aberrant behavior in
9 chronic opioid therapy patients that was
10 reported to be 45 percent of the sample
11 over a six-month period?

12 A. I don't understand your
13 question.

14 Q. Did you do any follow-up to
15 try to determine where this data was
16 coming from, the aberrant behavior in
17 chronic opioid therapy patients over a
18 six-month period where it appears that
19 45 percent of that sample group had
20 aberrant behavior?

21 A. Did I do any personal
22 follow-up?

23 Q. Correct.

24 A. No, I did not.

1 Q. Why is that?

2 A. Because these were our
3 experts and they came in with this
4 information and were informing us based
5 on what their experience and their
6 reading was. And the goal of the Ad
7 Board, as I've already discussed with
8 you, and you already mentioned, and it
9 seems to come up with a series of
10 studies. So it was framing out some of
11 the very best information to see what are
12 the types of studies that would need to
13 be done.

14 So this was background based
15 on someone that already had clinical
16 experience or what they had -- so we
17 didn't go and validate each of the
18 statements of these people. These were
19 world experts that were invited to this
20 meeting for this reason.

21 Q. So you -- you accepted this
22 as valid information from these key
23 opinion leaders?

24 MR. LIFLAND: Object to the

1 form of the question.

2 THE WITNESS: It was
3 information that we -- we -- it
4 was information that the experts
5 had brought to us and we took it
6 as part of the information that --
7 to -- to gain -- to be able to
8 develop the studies that we've
9 already talked about.

10 BY MS. CONROY:

11 Q. Okay. It was your belief if
12 you needed to know more about it, you
13 could just call any one of these key
14 opinion leaders and they could have given
15 you that citation or whatever they were
16 basing that information on?

17 A. If there was a need to
18 follow up on it for a specific reason, we
19 would have an opportunity to discuss that
20 with them if we needed to.

21 Q. Right, because you didn't
22 believe that you actually needed to
23 validate it. You accepted it as valid
24 when it was given to you?

1 MR. LIFLAND: Object to the
2 form of the question.

3 THE WITNESS: I think I've
4 already sort of addressed the
5 question, that these were -- these
6 were experts providing their
7 information, and I would not have
8 any reason not to believe what
9 they were suggesting.

10 Again, I could go -- we
11 could go back and do more if we
12 had a reason, which it didn't.

13 BY MS. CONROY:

14 Q. Okay. Page 28. This is a
15 discussion based on Dr. Vaughan's
16 icebreaker about nationally available
17 datasets. And what I want to ask you, in
18 your work at Janssen, were you ever
19 familiar with what's listed here as the
20 ARCOS data, A-R-C-O-S? Is that anything
21 that you ever worked with or were
22 familiar with?

23 A. I was familiar with it. I
24 did not work with it.

1 Q. Okay. How did you become
2 familiar with it?

3 A. I learned about it as an
4 informational database managed by DEA.

5 Q. Did you ever have occasion
6 to use any of the data from ARCOS for any
7 purpose?

8 A. It was used as part of the
9 information to monitor -- to monitor
10 about the availability of opioid. But I
11 did not work with the database myself
12 directly.

13 Q. Okay. How about MPA? Did
14 you ever use that database?

15 A. I don't recall what MPA
16 stands for.

17 Q. And it says that MPA looks
18 at the number of prescriptions, and then
19 if you look further on to Page 30. It
20 says, "MPA helps us look at how many
21 prescriptions are being written." Is it
22 possible that this is another acronym for
23 IMS? Or is that what you understand IMS
24 to provide?

1 A. I don't know.

2 Q. Okay. But MPA doesn't ring
3 a bell with you?

4 A. Not at this point.

5 Q. And would you agree with the
6 statement on Page 30 or have any reason
7 to doubt the statement that, "ARCOS is
8 the only way that we can track where
9 these drugs are moving around the nation
10 and in certain cases it's quite
11 informative to pinpoint where are the hot
12 spots of where these drugs are moving."

13 Any reason to disagree with
14 that?

15 A. I don't have an opinion on
16 that at this point.

17 Q. And you did at this point in
18 2003, you had ARCOS data available to you
19 at Janssen?

20 A. I don't remember when I
21 started looking at ARCOS and when I
22 became aware of it.

23 Q. At some point in your tenure
24 you had availability to ARCOS?

1 A. At some point in my -- when
2 I -- working at Janssen, I became aware
3 of ARCOS and the type of data that it
4 tracks.

5 Q. And did I understand you to
6 say that at some point you used some of
7 that data?

8 A. No, I did not. My testimony
9 is I did not use ARCOS myself.

10 Q. Look at Page 32. Up at the
11 top. And I will tell you that this is --
12 if I can find it. I'm not sure which
13 doctor's icebreaker this is. But the
14 reference is, "Among those people who
15 misuse, what's the probability that you
16 become dependent?"

17 It says, "About half of
18 heroin misusers are dependent, so you can
19 look at about a 50 percent chance of
20 becoming dependent, and opioids just
21 about an 8 percent chance."

22 Do you see that?

23 A. I do.

24 Q. And is this the same answer,

1 that you would have accepted these
2 numbers as provided?

3 A. These would -- again, as
4 I've already provided testimony, this was
5 the information that came in from our key
6 opinion leaders participating at the
7 meeting, and this was what their various
8 understanding would be. I don't
9 comment -- I don't have a comment on the
10 numbers, per se at this point.

11 Q. Okay. Turn to Page 47.
12 This is the section on, "Can we all agree
13 on one definition of addiction?"

14 Do you see that?

15 A. Yes.

16 Q. "ASAM and the American Pain
17 Society" -- I still don't see what's
18 telling us what ASAM means.

19 MR. LIFLAND: What page?

20 MS. CONROY: 47.

21 BY MS. CONROY:

22 Q. It says, "The American
23 Academy of Pain Medication, that's one
24 definition I will describe." And you see

1 that definition there in the middle of
2 the page?

3 A. Yes.

4 Q. And then it goes on to the
5 DSM-IV definition of dependent syndrome
6 and the International Classification of
7 Diseases" -- and that's an IDC -- ICD-10.

8 Do you see that?

9 A. Mm-hmm, right.

10 Q. You're familiar with all
11 three of those?

12 A. I'm not sure what you're
13 asking me.

14 Q. Are you familiar with the
15 three different definitions of
16 addiction/substance dependence?

17 A. I'd have to look at it and
18 see which ones they are. I'm certainly
19 familiar with the first one.

20 Q. Okay. You're familiar with
21 the ASAM definition?

22 A. Yes. This was -- yes, as
23 described here.

24 Okay.

1 Q. Do you have a go-to
2 definition yourself?

3 A. I tend to use the one that
4 was -- that came up with the ACTION --
5 that we talked about at the ACTION
6 group. I liked that one. And I like the
7 one that was used by these organizations.
8 I think the American Pain Society, APM.
9 I think this is -- this is a nice
10 characterization.

11 Q. And that's instead of the
12 DSM-IV?

13 A. This is the one I'm more
14 familiar with. I wouldn't -- I can't
15 comment on one being better or worse. I
16 think your question to me was which one
17 do I favor. This is the one that I have
18 seen.

19 Q. Okay. The ASAM and the
20 American Pain Society?

21 A. I'm not as familiar with the
22 DSM-IV. So it's not one that I would
23 necessarily gravitate to. But it's
24 another definition.

1 Q. Okay. Turn to Page 63.

2 This is looking at "Outcome measures in
3 clinical trials relevant to addiction to
4 opioids in chronic pain patients based on
5 Bruce Rounsaville's icebreaker."

6 And if you take a moment to
7 take a look at this page. He's talking
8 about what types of things you would
9 measure to measure addiction to opioids
10 in chronic pain patients.

11 Do you see that?

12 A. Mm-hmm, yes.

13 Q. And he says, "In substance
14 abuse studies, what we typically do is
15 take a bunch of people who are already
16 addicted or who want to stop or who have
17 either stopped or we're trying to get
18 them to stop, and so most of our measures
19 really are relevant for that sort of
20 situation," which would be to stop
21 treatment altogether, correct?

22 MR. LIFLAND: Object to
23 form.

24 BY MS. CONROY:

1 Q. For the substance abuse
2 studies?

3 MR. LIFLAND: Object to the
4 form of the question.

5 THE WITNESS: It doesn't
6 talk, that I've seen, about what
7 action would be taken.

8 BY MS. CONROY:

9 Q. Okay. Well, then maybe he
10 makes it clearer. He says, "As opposed
11 to taking a bunch of people, and you're
12 giving them medication for a particular
13 legitimate problem, chronic pain, and
14 then our outcome is going to be whether
15 they get into trouble or not."

16 Do you see that?

17 A. Yes.

18 Q. And that trouble would be
19 some sort of adverse event like addiction
20 or abuse?

21 A. I don't have the full
22 context to be able to comment on that.

23 Q. Okay. If you take a look at
24 Page 72, where we begin to see some

1 recommended clinical studies.

2 They say, "Recommendations
3 to Janssen." And the key opinion leaders
4 recommend that in any study that you do,
5 on the use or the abuse of opioids in
6 pain settings, it's crucially important
7 that the measure that is used is the
8 addiction severity index.

9 Do you see that?

10 A. Yes.

11 Q. Are you familiar with that?

12 A. Briefly.

13 Q. Have you ever designed or
14 reviewed a clinical trial that used an
15 addiction severity index?

16 A. No. A study -- this may
17 have been -- and I have to check and get
18 additional documentation to confirm, that
19 this type of information may have been
20 captured in the Inflexxion studies. But
21 I would need to have additional
22 information to confirm that. But I did
23 not do any -- I have not done clinical
24 studies myself.

1 Q. If it's in the Inflexxion
2 study, that would be potentially data
3 that you've seen but you would not have
4 had anything to do with the setup of the
5 Inflexxion studies?

6 A. That's correct, yes. And I
7 did not use it in clinical studies
8 myself, which was your question to me.

9 Q. Okay. And as far as you
10 know, Janssen has never used -- or J&J or
11 Janssen has never used the addiction
12 severity index in any clinical trials
13 that it either sponsored or accepted by
14 an investigator?

15 MR. LIFLAND: Object to the
16 form of the question.

17 THE WITNESS: To the best of
18 my knowledge, I have not seen
19 studies from Janssen where the
20 addiction severity index was used
21 in a controlled clinical trial.

22 BY MS. CONROY:

23 Q. When you say controlled
24 clinical trial, are you making a

1 distinction between a controlled clinical
2 trial and just a clinical trial?

3 A. No. The same -- clinical
4 trial.

5 Q. Same -- okay.

6 A. I'm using them
7 interchangeably at this point.

8 Q. Take a look at Page 132.
9 And this discusses a fifth clinical trial
10 to derive signals that are suggestive of
11 greater -- suggestive of greater or
12 lesser abuse liability from clinical
13 trials. And it lists some signals. Do
14 you see that?

15 A. Yes.

16 Q. Do you have any -- do you
17 know whether anything like this has been
18 done going back to clinical trials to see
19 if such signals exist at Janssen, Johnson
20 & Johnson?

21 A. I'm unaware of that. I
22 don't -- I don't know.

23 Q. Would you have been aware of
24 it at least up through 2013-2014, if

1 there was anything underway to look for
2 abuse liability signals in clinical
3 trials that had been conducted with
4 respect to any J&J or Janssen opioids?

5 MR. LIFLAND: Object to the
6 form of the question.

7 THE WITNESS: I'm unable to
8 comment on that.

9 BY MS. CONROY:

10 Q. Why not?

11 A. Because I would have to have
12 an understanding of all of the studies
13 that are being done. So it's possible.
14 But on the other hand, I may not.

15 Q. Do you think that there
16 could have been, between the years 2000
17 and 2015, an analysis of clinical trials
18 at Janssen, Johnson & Johnson, looking
19 for signs at iatrogenic addiction and you
20 didn't know about it?

21 A. It's likely that I would
22 have heard about it. But again, looking
23 at the nature of the design of those
24 studies and how it would need to be done,

1 it would be -- would be difficult to do.

2 Q. That's not my question, not
3 how difficult it is. My question was
4 simply, if there was a study being
5 performed or a group of studies at
6 Johnson & Johnson, Janssen, with respect
7 to iatrogenic addiction and opioids, is
8 it something you would have known about?

9 A. Possibly.

10 Q. Under what circumstances
11 would you not know about it?

12 MR. LIFLAND: Object to the
13 form of the question.

14 THE WITNESS: I -- it
15 depends on the nature of the
16 design and who was doing it.
17 You -- frequently I would be
18 consulted, but not always.

19 BY MS. CONROY:

20 Q. Who would I -- who would I
21 ask to find out if there have been
22 studies with respect to iatrogenic
23 addiction to opioids, whether those were
24 studies to go back and look at signals in

1 existing clinical trials or new studies
2 that were being conducted, if not you,
3 who should I talk to?

4 A. I don't know today.

5 Q. Who would I have talked to
6 in 2013?

7 A. Maybe some people in the
8 epidemiology group, but it could have
9 very well have been me, again. But it
10 doesn't necessarily have to be me.

11 Q. I understand that. What I'm
12 trying to understand is here in 2003,
13 there is a discussion about how to go
14 back and look for signals in clinical
15 trials that had been conducted for signs
16 of iatrogenic addiction, unwarranted dose
17 escalation, and other items by Johnson &
18 Johnson, Janssen key opinion leaders.
19 And this is in 2003.

20 A. Right.

21 Q. If this was followed through
22 and some of these studies were done, or
23 just one of these studies were done, who
24 would have known about it?

1 A. I was someone who might have
2 known about it, and I was not aware of
3 such a study being done.

4 Q. Is there someone I'm
5 missing?

6 A. At this point, I don't know.

7 Q. You don't know between 2015
8 to 2017?

9 A. I don't know between 2015
10 and 2017. And I don't know, as I had
11 commented, these studies, if they were
12 going to be done, may be done with a
13 number of different people at the
14 company.

15 Q. So who are -- who are the
16 number of different people that would be
17 doing them that you wouldn't know about?

18 A. As I said, it would be
19 likely that I would know about it, but
20 there may have been studies done by other
21 groups as well. I'm not aware of it. I
22 think my -- so my testimony is I wasn't
23 aware of such studies being done. But
24 could they have been done by other

1 people? Possibly. I don't know.

2 Q. But you understand if I'm
3 trying to look to see if Johnson &
4 Johnson did any studies like this --

5 A. Yes.

6 Q. -- it's not particularly
7 useful for me for you to say maybe there
8 were others and I'm just not looking in
9 the right place. So I'm trying to figure
10 out. I understand you're not aware of
11 any studies that did this, correct?

12 A. Correct.

13 Q. But you're telling me that
14 maybe they were somewhere in the company?

15 MR. LIFLAND: I'm going to
16 object to the form of the
17 question.

18 THE WITNESS: I probably
19 would have known about such
20 studies if they would have taken
21 place. But I can't say with
22 absolute certainty that such
23 studies weren't done.

24 BY MS. CONROY:

1 Q. And do you have a feel for
2 where I would look to -- to be
3 100 percent sure that these studies were
4 not done?

5 A. No, I'm not. I'm not sure
6 where you would look.

7 Q. They would have been
8 budgeted, right?

9 A. They might have been
10 budgeted, yes.

11 Q. Wouldn't they have to be
12 budgeted?

13 A. Yes, yeah. Somebody would
14 have to pay for it. Absolutely. Yes.

15 Q. And they wouldn't be secret?

16 A. No, absolutely not. And
17 they would have been published if the
18 studies were undertaken. And I'm not
19 aware of those publications.

20 Q. You can put that document
21 away.

22 MR. LIFLAND: We are coming
23 close to 5 o'clock. I don't think
24 I want to go too much longer

1 today. We've got tomorrow set
2 aside.

3 MS. CONROY: How about if
4 we -- I just have some more about
5 this ad group, some additional
6 documents, we just finish up this
7 section. Are you okay?

8 MR. LIFLAND: Are you okay
9 going a little bit more?

10 THE WITNESS: Yes.

11 MR. LIFLAND: That's fine.

12 MS. CONROY: Then we can
13 just finish it off.

14 (Document marked for
15 identification as Exhibit
16 Janssen-Vorsanger-10.)

17 BY MS. CONROY:

18 Q. I'm marking Exhibit 10.

19 JAN-MS-00613131. Careful of the staple
20 on these.

21 This is an e-mail from just
22 before the -- right around the time that
23 you were setting the Ad Board up in
24 September of 2003. And this is an e-mail

1 from Dr. Katz to you. The Re line is
2 abuse stuff. And he's attached a
3 proposal for a review article on
4 prescription opioid abuse, current
5 methodology and research agenda. Do you
6 see that?

7 A. Yes.

8 Q. And you forwarded that on to
9 Clare Harte, who is also in your
10 department, correct?

11 A. That's correct, yes.

12 Q. Had you requested that
13 Dr. Katz provide you with this proposal?
14 Is that -- or is that the usual way that
15 it would work?

16 A. Usually we would if there's
17 an area of interest and Dr. Katz knew
18 that I had an interest in abuse
19 culminating on the advisory board. So --
20 but I can't -- I don't recall at this
21 time whether I'd asked for it or whether
22 he knew I was interested and provided me
23 with this.

24 Q. And the -- the purpose --

1 the goal of the article was to review for
2 the pain management community the
3 critical concepts of prescription opioid
4 abuse. Review the current status of
5 knowledge about prescription opioid abuse
6 in the community --

7 A. I'm sorry, where are you
8 reading? I'm sorry.

9 Q. Right under Roman Numeral I.

10 A. Okay.

11 Q. Okay?

12 So he -- he lays out the
13 goals of the article.

14 A. Right.

15 Q. And then he says, "The
16 purpose is to prepare the minds of the
17 pain management community to expect and
18 value certain types of data in order to
19 be persuaded that one modified release
20 opioid product is less abusable/abused
21 than another."

22 Do you see that?

23 A. I do.

24 Q. And this was to position a

1 Johnson & Johnson product in the market
2 so long as the clinical study was
3 accepted by the FDA for this purpose as
4 less abusable than a comparator product,
5 correct?

6 A. I was to provide data so
7 that people can begin to understand the
8 type of information that would be needed
9 for them to make an informed decision on
10 which of the opioids would be appropriate
11 for those patients that they have.

12 Q. And then following along
13 with that, you would have identified a
14 Johnson & Johnson product as being less
15 abusable using those criteria?

16 A. If the data was supported
17 and FDA agreed on it, then the correct
18 studies would need to be done.

19 Q. Were any such studies done?

20 A. Not to my knowledge.

21 Q. Do you know if any -- do you
22 know if the criteria was ever developed,
23 or what types of data would be used to
24 determine that?

1 A. I need to see where this is
2 in position to the advisory board.

3 Q. Sure.

4 A. That would be good. So the
5 e-mail that you're talking about now is
6 from the 23rd of September of '03, and
7 then early in January, and we had the Ad
8 Board in November.

9 Q. Right. So this -- this was
10 around the time that we saw some e-mails
11 between you, Dr. Sacoer, and Dr. Katz
12 kind of laying out the program?

13 A. Right. So I think the
14 dialogue was, this is some of the things
15 that we can think about. And this may
16 have morphed into the advisory board.
17 Let's get some other people's opinion.
18 Let's understand the state of the art.
19 What are the things that people need to
20 be thinking about, and what are the types
21 of studies that would need to be done.

22 Q. I see. So this may in fact
23 have been the genesis for the Ad Board?

24 A. I had interest in doing this

1 as well, but this may have been certainly
2 part of the original conversations
3 related and tied into the advisory board
4 later on, yes.

5 Q. Okay. The RADARS data and
6 the Inflexxion data, did that become --
7 did those organizations develop data that
8 could be used to determine whether one
9 product is more or less abusable than
10 another?

11 A. The RADARS data and the
12 Inflexxion data are monitoring programs
13 and would be part of other data that
14 would be presented to FDA as part of a
15 package.

16 Q. And I understand that you
17 told me earlier that RADARS and
18 Inflexxion data could not be used in a
19 promotional venue to discuss the relative
20 abuse liability of a particular opioid,
21 correct?

22 A. Yes.

23 Q. Do you know if the RADARS or
24 Inflexxion data, however, was an attempt

1 to come up with a type of data that could
2 then be used as criteria for a clinical
3 study on what would be more or less
4 abusable?

5 A. No. I think the RADARS data
6 and the Inflexxion data would have been
7 used as part of a package with other
8 information to inform the FDA as kind of
9 a suite of information to them to talk
10 about an abuse of liability. But the
11 RADARS and Inflexxion data to my
12 recollection were not used specifically
13 to design a clinical trial.

14 Q. And we looked at the
15 document that was the PowerPoint slide
16 that had one of the strategic drivers was
17 to show lower abuse potential of the
18 Johnson & Johnson opioid product.

19 Do you recall that?

20 A. Yes.

21 Q. And was that -- did that
22 come out of this type of proposal, do you
23 know, that driver?

24 A. I'm not completely following

1 your question, I'm sorry.

2 Q. Okay. Was this something
3 that was in the works for quite some time
4 to try to determine what type of -- what
5 types of datasets could determine lower
6 abuse potential of a Johnson & Johnson
7 product?

8 A. I don't remember how long
9 that was in the works. There was a lot
10 of interest in understanding the type of
11 abuse programs that would need to be done
12 which culminated into the advisory board.
13 But to answer your question, I don't know
14 how long that was in the works.

15 Q. Do you know when RADARS and
16 Inflexxion data began to be provided to
17 the FDA by Johnson & Johnson?

18 A. Shortly after we started
19 using those programs, that would have
20 been provided in either safety type
21 reports and as a way of communicating
22 what we were monitoring.

23 Q. And were you involved in
24 that or was that a different department?

1 A. No, I was involved with
2 that.

3 Q. Were you involved with
4 Duragesic, or was it with Nucynta?

5 A. I was involved in -- I'm
6 sorry, Counsel. I'm not understanding
7 your question.

8 Q. In providing RADARS and
9 Inflexxion data with respect to abuse
10 liability or surveillance information
11 provided to the FDA, were you involved
12 for all opioid products at Johnson &
13 Johnson, or did you have involvement with
14 providing that data for Duragesic or
15 Nucynta or something else?

16 A. Initially, all opioid
17 products.

18 Q. Okay. So it was -- it was a
19 classwide submission?

20 A. These were activities that
21 the company initiated without a
22 requirement to do so, to monitor opioid
23 analgesics, correct.

24 Q. And around when did that

1 begin?

2 A. When the RADARS data became
3 available to us, which was approximately
4 2006 or thereabouts.

5 Q. But no clinical studies had
6 been done using that data to date that
7 you're aware of?

8 A. No, not that I'm aware of.

9 Q. At Johnson & Johnson?

10 A. At Johnson & Johnson,
11 correct.

12 (Document marked for
13 identification as Exhibit
14 Janssen-Vorsanger-11.)

15 BY MS. CONROY:

16 Q. This is likewise in that
17 same time period, marked as Exhibit 11.
18 JAN-MS-006132014 through -- I think we've
19 got a native document here. Well that's
20 the cover Bates range. I'm not sure.
21 The rest of it doesn't have a Bates
22 number on it.

23 That's Exhibit 11.

24 A. Okay.

1 Q. There might be a native slip
2 sheet in there somewhere. This is an
3 e-mail dated November 13th of 2003,
4 forwarding a draft of the study outlines
5 from you to Tricia Haertlein and Surya
6 Vangala. Surya worked in your
7 department?

8 A. Yes, she did.

9 Q. What about Tricia?

10 A. They both did. Tricia
11 Haertlein was an administrative
12 assistant. And Surya Vangala was a
13 project -- project manager.

14 Q. Okay. And you say,
15 "Attached, please find the draft of Nat's
16 paper." That's Dr. Katz, right?

17 A. Yes.

18 Q. "I'm making changes to the
19 document, and Nat will be creating a
20 draft PowerPoint presentation."

21 Do you see that?

22 A. Yes.

23 MS. CONROY: Okay. Here is
24 the slip sheet for the --

1 Doctor, this won't make any
2 difference to you.

3 But the slip sheet for the
4 attachment to that e-mail is
5 JAN-MS-00613205.

6 BY MS. CONROY:

7 Q. If you turn the page, in
8 this document, Dr. Katz was providing
9 more detail about the consensus meeting;
10 is that correct?

11 A. Yeah.

12 Q. It was about a week later,
13 or maybe almost two weeks later, and he
14 was developing a PowerPoint.

15 Do you know who the
16 PowerPoint was going to be shown to?

17 A. I don't recall.

18 Q. With Slide 2, he says, "The
19 results of the meeting, the key points.
20 The group did come to consensus on a
21 suite of studies."

22 A. Yes.

23 Q. "These studies should be
24 divided into two groups by timetable" --

1 "by timeline, those that could
2 potentially be completed in less than a
3 year. That would be abuse liability
4 studies, for example studies to predict
5 actual abuse.

6 "And two, those that would
7 require more than a year, studies of
8 actual abuse."

9 Do you see that?

10 A. Yes.

11 Q. And do you agree with that
12 timeline?

13 A. Yes. That was a timeline we
14 wanted them to organize the studies by.

15 Q. And then he says in Roman
16 Numeral II-C, "The group agreed that
17 measures of actual abuse in the target
18 population, patients with chronic pain on
19 opioids and the community, were of
20 greater importance than studies of abuse
21 liability, which are designed to predict
22 actual abuse."

23 Do you see that?

24 A. Yes.

1 Q. And are you in agreement
2 with that, that actual abuse measurements
3 would be of greater importance to
4 physicians and payers than abuse
5 liability studies?

6 A. I think both sets of studies
7 are important, but there was a paucity
8 information about what was going on in
9 the community. So there was strong
10 interest in getting information on the
11 actual community. That's what Dr. Katz
12 identifies here.

13 Q. And then --

14 A. But certainly both of them
15 are -- will be needed to have a robust
16 package of information to talk about
17 abuse liability.

18 Q. Right. And he says that.
19 Both are important.

20 A. Yes.

21 Q. But he says the actual abuse
22 was considered to be of greater
23 importance than the also important abuse
24 liability study.

1 A. Yes, that was his -- if that
2 was the conclusion of the meeting, then,
3 yeah.

4 Q. Okay. And what do you mean
5 by "and the community"? What was the
6 strong interest in the community? What
7 do they want to know?

8 A. The people being treated
9 with the drugs, as opposed to doing abuse
10 liability studies, some of which may be
11 done in the laboratories for example.

12 Q. So it would be actual
13 studies of pain patients in a particular
14 community, either low back pain
15 community, sickle cell community --

16 A. Patients with pain.

17 Q. -- whatever?

18 A. Patients with pain, people
19 with pain, chronic pain, who are on
20 medications to treat their chronic pain.

21 Q. And those studies were never
22 done, correct, as far as you know?

23 A. To the best of my knowledge,
24 those studies were not done.

1 Q. Okay. And that's both the
2 actual abuse studies as well as the abuse
3 liability studies designed to predict
4 actual abuse, correct?

5 A. There were abuse
6 liability-type studies that were done for
7 tapentadol ER. There were studies that
8 evaluated ways in which people might
9 abuse those. So those were abuse
10 liability studies, again for tapentadol.
11 So those were done later on in the
12 other -- in another product.

13 Q. Was that abuse liability of
14 the drug itself or the abuse liability in
15 the patient community?

16 A. The abuse liability studies
17 would have been how -- which -- which
18 could be used to predict actual abuse.
19 So some of those may be -- to my best
20 understanding is some of those may be
21 laboratory-type studies. And they may
22 also be studies in which they take people
23 who are abusers of the medications and
24 see how they might go about abusing the

1 medication.

2 Q. How they would tamper with
3 it, correct?

4 A. Yes, that's correct.

5 Q. But as far as you know,
6 there were no -- there were no abuse
7 liability studies conducted in the
8 patient community concerning tapentadol
9 ER?

10 A. I think we are talking
11 about, tapentadol was not -- we're
12 talking about Duragesic at this point.

13 Q. Okay.

14 A. Yeah.

15 Q. But even -- but even to
16 this -- until 2015, regardless of the
17 drug, no such actual abuse or abuse
18 liability community studies have been
19 done for any Johnson & Johnson, Janssen
20 opioid product?

21 A. There were abuse liability
22 studies --

23 MR. LIFLAND: Object to the
24 form of the question. Sorry, you

1 can answer.

2 THE WITNESS: There were
3 abuse liability studies, I
4 believe, that were done for
5 tapentadol. I think, given the
6 years here in '03, my focus might
7 be on Duragesic. And as far as I
8 know for Duragesic I don't recall
9 such studies.

10 BY MS. CONROY:

11 Q. Okay. In the tapentadol ER
12 studies, you recall lab studies and then
13 some studies that were done of
14 individuals who misused and abused the
15 product to determine how tamper resistant
16 the drug is?

17 A. That's my -- I would have to
18 see documentation, but that was the
19 recollection that I have to support my
20 statement.

21 Q. Okay. Do you have any
22 recollection of there being a study using
23 tapentadol ER of chronic pain patients in
24 the -- in the community to determine or

1 predict abuse liability in a community of
2 pain patients?

3 A. Not that I recall.

4 Q. And if you could turn to --
5 let's see. It's number -- it's D.

6 A. 1D did you say?

7 Q. It was just -- you'll see
8 there's a page that say C, "Ease of
9 extraction of active product." Then if
10 you turn the page it says D, "Validation
11 of abuse-related constructs and outcome
12 measures"?

13 A. Yes.

14 Q. Did you find that?

15 A. I do see that, yes.

16 Q. Okay. And it says, "Brief
17 description of the nature and purpose of
18 the studies. The group recognized that
19 ultimately randomized controlled clinical
20 trials and epidemiological studies will
21 be the final arbiters of differences in
22 abuse liabilities between MROs. The
23 group also recognized the fact there's
24 little agreement on what outcomes should

1 be measured in such trials, terms such as
2 'abuse,' 'misuse,' 'aberrant drug
3 behaviors,' 'recreational use,' extra
4 medical abuse,' independence,' are often
5 bandied about, but there's little
6 agreement on what the syndromes of
7 concern are, what they should be called,
8 and there's absolutely no empiric work in
9 this area to define these syndromes."

10 Do you agree with that?

11 Or I'm sorry, do you see
12 that?

13 A. Yes.

14 Q. And this is --

15 A. To answer your question, I
16 agree that this is what the group
17 consensus came up with.

18 Q. Okay. And so this was --
19 this was Dr. Katz's outline of what the
20 group came up with, and we also have the
21 January Dr. Sacoer consensus, and they --
22 they pretty much mesh.

23 Would you agree?

24 A. Yes.

1 Q. It goes on and says,
2 Dr. Katz says, "Furthermore, there's been
3 little work on predictors of negative
4 outcomes of opioid therapy or of opioid
5 abuse in the community. No credible
6 clinical trial or epidemiological study
7 can proceed without preceding work done
8 on construct validation and instrument
9 develop" -- "development to measure these
10 constructs and predictors."

11 Do you see that?

12 A. Yes.

13 Q. And that would mean that you
14 would have to come up with some
15 definition that you were going to use and
16 some way of validating the work, correct?

17 A. Yes.

18 Q. And that's what this ad
19 group was looking at, ways to construct
20 those types of studies, correct?

21 A. Yes.

22 Q. Is there a reason why those
23 studies did not proceed?

24 A. The -- the decision was that

1 we were going to focus on certain types
2 of studies that we -- that would be able
3 to provide some information to us around
4 abuse liability, so based on competing
5 priorities of what might be going on in
6 terms of clinical trials, et cetera.

7 Q. So the -- the reason there
8 were -- there were competing priorities
9 was --

10 A. There may have been at the
11 time. Yeah. Yes.

12 Q. Let me just finish the
13 question.

14 So there were -- as best you
15 understand, there were competing
16 priorities with respect to which studies
17 Johnson & Johnson would go forward with
18 at the time and that's why the studies
19 that were discussed at the Ad Board did
20 not go forward?

21 A. Some of the work did go
22 forward. I think there was some work
23 that went on to look at likability. I
24 think that was one of the projects that

1 came out of some of this discussion. So
2 I believe some of the studies were done.
3 But all of the studies were not
4 implemented.

5 Q. And the likability studies
6 were the -- the lab studies with respect
7 to how easy it was to crush or
8 dissolve --

9 A. Those were later, those were
10 later in other compound. But I think
11 there was one looking at differences on
12 the different types of formulations, but
13 I'd have to check on that.

14 Q. Okay. Were those studies
15 done by Johnson & Johnson?

16 A. Those were studies that were
17 done by other people.

18 Q. Were there individuals or
19 patients that were used in those studies
20 or were they lab studies?

21 A. I don't recall.

22 Q. Okay. You can put that one
23 away.

24 MS. CONROY: We'll end for

1 the day.

2 MR. LIFLAND: Okay.

3 MS. CONROY: Thank you,
4 Doctor.

5 MR. LIFLAND: We'll come
6 back tomorrow.

7 THE VIDEOGRAPHER: Stand by
8 please. Remove your microphones.

9 The time is 5:23 p.m. Going
10 off the record.

11 (Excused.

12 (Adjourned at approximately
13 5:23 p.m.)

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1
2 CERTIFICATE
3
4

5 I HEREBY CERTIFY that the
6 witness was duly sworn by me and that the
7 deposition is a true record of the
8 testimony given by the witness.

9 It was requested before
10 completion of the deposition that the
11 witness, GARY J. VORSANGER, Ph.D., M.D.,
12 have the opportunity to read and sign the
13 deposition transcript.

14
15 _____
16 MICHELLE L. GRAY,
17 A Registered Professional
18 Reporter, Certified Shorthand
19 Reporter, Certified Realtime
20 Reporter and Notary Public
21 Dated: December 10, 2018
22
23
24

25 (The foregoing certification
26 of this transcript does not apply to any
27 reproduction of the same by any means,
28 unless under the direct control and/or
29 supervision of the certifying reporter.)
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32

1 INSTRUCTIONS TO WITNESS

2
3 Please read your deposition
4 over carefully and make any necessary
5 corrections. You should state the reason
6 in the appropriate space on the errata
7 sheet for any corrections that are made.

8 After doing so, please sign
9 the errata sheet and date it.

10 You are signing same subject
11 to the changes you have noted on the
12 errata sheet, which will be attached to
13 your deposition.

14 It is imperative that you
15 return the original errata sheet to the
16 deposing attorney within thirty (30) days
17 of receipt of the deposition transcript
18 by you. If you fail to do so, the
19 deposition transcript may be deemed to be
20 accurate and may be used in court.

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2 ACKNOWLEDGMENT OF DEPONENT

3
4 I, _____, do
5 hereby certify that I have read the
6 foregoing pages, 1 - 419, and that the
7 same is a correct transcription of the
8 answers given by me to the questions
9 therein propounded, except for the
10 corrections or changes in form or
11 substance, if any, noted in the attached
12 Errata Sheet.

13
14
15 _____
16 GARY J. VORSANGER, Ph.D., M.D. DATE

17
18
19 Subscribed and sworn
20 to before me this

21 _____ day of _____, 20____.

22 My commission expires: _____

23 _____
24 Notary Public

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